



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Cleaning up and revitalizing land

EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health and the Environment

Report No. 19-P-0002

November 15, 2018



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Abbreviations

CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General
POTW	Publicly Operated Treatment Works
RCRA	Resource Conservation and Recovery Act
USGS	U.S. Geological Survey

Cover Photo: Tilling soil and injecting biosolids into a farm field near Madison, Wisconsin.
(OIG photo)

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At a Glance

Why We Did This Review

We conducted this audit to determine whether the U.S. Environmental Protection Agency (EPA) has and implements controls over the land application of sewage sludge that are protective of human health and the environment.

Sewage sludge is the solid, semisolid or liquid residue generated during the treatment of domestic sewage. When sludge materials go through additional processing steps and treatment to meet EPA standards for land application, they are referred to as biosolids. Treatment is used to reduce the concentration of disease-causing organisms, called pathogens, and to reduce the attractiveness to mosquitoes, flies, fleas, rodents and birds, as well as other disease-carrying organisms. If the resulting product meets regulatory standards, the product can be used for agricultural and residential soil fertilization.

This report addresses the following:

- *Cleaning up and revitalizing land.*

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EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health and the Environment

What We Found

The EPA's controls over the land application of sewage sludge (biosolids) were incomplete or had weaknesses and may not fully protect human health and the environment. The EPA consistently monitored biosolids for nine regulated pollutants. However, it lacked the data or risk assessment tools needed to make a determination on the safety of 352 pollutants found in biosolids. The EPA identified these pollutants in a variety of studies from 1989 through 2015. Our analysis determined that the 352 pollutants include 61 designated as acutely hazardous, hazardous or priority pollutants in other programs.

The EPA identified 352 pollutants in biosolids but cannot yet consider these pollutants for further regulation due to either a lack of data or risk assessment tools. Pollutants found in biosolids can include pharmaceuticals, steroids and flame retardants.

The Clean Water Act requires the EPA to review biosolids regulations at least every 2 years to identify additional toxic pollutants and promulgate regulations for such pollutants. Existing controls based on the Clean Water Act and the EPA's Biosolids Rule include testing for nine pollutants (all heavy metals), researching for additional pollutants that may need regulation, reducing pathogens and the attractiveness of biosolids to potential disease-carrying organisms, and conducting compliance monitoring activities. The EPA's risk communication regarding biosolids should also be transparent.

The EPA has reduced staff and resources in the biosolids program over time, creating barriers to addressing control weaknesses identified in the program. Past reviews showed that the EPA needed more information to fully examine the health effects and ecological impacts of land-applied biosolids. Although the EPA could obtain additional data to complete biosolids risk assessments, it is not required to do so. Without such data, the agency cannot determine whether biosolids pollutants with incomplete risk assessments are safe. The EPA's website, public documents and biosolids labels do not explain the full spectrum of pollutants in biosolids and the uncertainty regarding their safety. Consequently, the biosolids program is at risk of not achieving its goal to protect public health and the environment.

Recommendations and Planned Agency Corrective Actions

We recommend that the Office of Water address control weaknesses in biosolids research, information sharing with the public, pathogen control and training. Further, we recommend that the Office of Water and Office of Enforcement and Compliance Assurance improve the consistency of compliance monitoring and better record inspection data. The EPA provided acceptable corrective actions and milestone dates in response to eight of the 13 recommendations. Those recommendations are resolved with corrective actions pending. Five of the recommendations in this report (7, 9, 10, 11 and 13) are unresolved with resolution efforts underway.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

November 15, 2018

MEMORANDUM

SUBJECT: EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health and the Environment
Report No. 19-P-0002

FROM: Charles J. Sheehan
Acting Inspector General

Charles J. Sheehan

TO: David P. Ross, Assistant Administrator
Office of Water

Susan Bodine, Assistant Administrator
Office of Enforcement and Compliance Assurance

This is our report on the subject audit conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this audit was OPE-FY17-0019. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Water's Office of Science and Technology and Office of Wastewater Management, the Office of Enforcement and Compliance Assurance, and the Biosolids Center of Excellence in Region 7 are the offices responsible for the issues discussed in this report.

Action Required

In accordance with EPA Manual 2750, acceptable corrective actions and milestone dates were provided in response to eight of the recommendations in this report. Those recommendations are considered resolved and no final response is required.

Five of the recommendations in this report—all addressed to the Assistant Administrator for Water—are unresolved. In accordance with EPA Manual 2750, the resolution process for unresolved recommendations begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the Assistant Administrator for Water and the OIG's Assistant Inspector General for Audit and Evaluation. If resolution is still not reached, the Assistant Administrator for Water is required to complete and submit a dispute resolution request to the Chief Financial Officer to continue resolution.

We will post this report to our website at www.epa.gov/oig.

Table of Contents

Chapters

1	Introduction	1
	Purpose	1
	Background.....	1
	Responsible Offices	9
	Noteworthy Achievements	9
	Scope and Methodology	9
	Prior Reports.....	11
2	EPA Lacks Data Needed to Determine the Safety of Pollutants in Biosolids	12
	Weaknesses in Health and Environmental Controls over Biosolids	12
	<i>EPA Oversees Required Testing for the Nine Regulated Pollutants</i>	<i>14</i>
	<i>Research Is Needed on over 300 Other Pollutants Found in Biosolids</i>	<i>14</i>
	<i>Unclear Pathogen Reduction and Sampling Methods Lead to Public Health Concerns</i>	<i>18</i>
	<i>EPA's Public Safety Statement Does Not Disclose Data and Risk Assessment Limitations</i>	<i>19</i>
	<i>Biosolids Labels Are Not Required to Disclose Additional Pollutants of Potential Risk to Users</i>	<i>21</i>
	<i>EPA Is Not Conducting Biosolids Training in Accordance with the Clean Water Act</i>	<i>22</i>
	<i>EPA and States Have Inconsistent Compliance Monitoring Goals and Methods</i>	<i>23</i>
	Conclusions	25
	Recommendations	26
	Agency Response and OIG Evaluation	27
	Status of Recommendations and Potential Monetary Benefits	31

- continued -

Appendices

A	Class A Pathogen Reduction Requirements	33
B	Prior OIG Reports	34
C	Unassessed Biosolids Pollutants Categorized as Hazardous or Toxic in Other Federal Programs	35
D	Agency Comments on Draft Report and OIG Evaluation	38
E	Revised Recommendations and Corrective Actions Plan	56
F	Distribution	60

Chapter 1

Introduction

Purpose

Our objective was to determine whether the U.S. Environmental Protection Agency (EPA) has and implements controls over the land application of sewage sludge that protect human health and the environment.

Background

Sewage sludge is the solid, semisolid or liquid residue generated during the treatment of domestic sewage. When the sludge materials go through additional processing steps and treatment to meet EPA standards for land application, they are referred to as biosolids. Throughout this report, we will refer to treated sewage sludge as biosolids.



Biosolids.
(EPA photo)

According to the EPA, when treated and processed, biosolids are nutrient-rich organic materials that can be applied as fertilizer to improve and maintain productive soils and stimulate plant growth. Specifically, biosolids improve soil properties, such as texture and water-holding capacity, which make conditions more favorable for root growth and increase the drought tolerance of vegetation. Biosolids application supplies nutrients essential for plant growth, including nitrogen and phosphorous, as well as some essential micronutrients such as nickel, zinc and copper. Nutrients in biosolids offer advantages over those in inorganic fertilizers because they are organic and released slowly to growing plants.

One purpose of the biosolids treatment is to significantly reduce the concentration of disease-causing organisms, also known as pathogens. Treatment also reduces the attractiveness of the residues to mosquitoes, flies, fleas, rodents, birds and other potential disease-carrying organisms—all referred to as vectors in the EPA's Biosolids Rule. Treated biosolids products meeting regulatory standards, as well as pathogen and vector attraction reduction requirements, may be sold for various uses, including agricultural and residential soil fertilization. If the biosolids do not meet land application standards, the treatment plant must dispose of the product in a landfill or incinerator.

Environmental and Health Considerations for Land-Applied Biosolids

Although they are treated, biosolids can still contain pollutants harmful to the environment and human health. Biosolids are a byproduct of wastewater treatment. Pollutants found in biosolids can include inorganic contaminants

(e.g., metals and trace elements); organic contaminants (e.g., polychlorinated biphenyls, known as PCBs; dioxins; pharmaceuticals and surfactants); and pathogens (e.g., bacteria, viruses and parasites).¹ According to the EPA, contaminants in a biosolids product will vary, depending upon the source of the biosolids and over time. The EPA stated that the occurrence of pollutants in biosolids does not necessarily mean that those pollutants pose a risk to public health and the environment. A 2002 report from the National Research Council of the National Academy of Sciences stated, “There is no documented scientific evidence that the [Biosolids Rule] has failed to protect public health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids.”²

A 2002 guidance document from the U.S. Centers for Disease Control and Prevention (CDC) provided guidance for controlling and preventing potential risks to workers from Class B³ biosolids.⁴ In this guidance document, the CDC provided background information on biosolids risks. It explained that there are four major types of pathogens that can be found in sewage—bacteria, viruses, protozoa and helminths (parasitic worms)—and that biosolids that are treated to a lower standard may contain the same types of pathogens as the wastewater sewage they originated from but at reduced concentrations.

The CDC also reported on whether these pathogens can cause disease, and found most of the pathogenic bacteria, viruses and parasites in biosolids are present in the intestinal tracts of humans and animals. These include, but are not limited to: *Escherichia coli* (*E. coli*), *Salmonella*, *Shigella*, *Campylobacter*, *Cryptosporidium*, *Giardia*, Norwalk virus and enteroviruses. People and animals exposed to these pathogens may become sick (e.g., with gastroenteritis) or carriers (i.e., the infection does not clinically manifest itself in the affected individual/animal but can be spread to others).

The CDC guidance document added that it is a prudent public health practice to minimize workers’ contact with Class B biosolids during production and application. It also stated that Class A biosolids can present a potential health risk since some chemicals and biologic constituents found in Class A biosolids are not regulated by the EPA. The guidance further stated that additional study of worker exposures to pathogens and other toxics possibly present in the Class B biosolids used by the workers is needed. This will reduce scientific uncertainty about these issues and allow further refinement of worker precautions.

¹ National Research Council of the National Academy of Sciences. *The Biosolids Applied to Land: Advancing Standards and Practices*. The National Academies Press. 500 Fifth Street, NW Washington, D.C. 20001 (2002).

² Ibid.

³ There are two categories of biosolids: Class A and Class B. These are discussed later in this chapter.

⁴ Department of Health and Human Services, CDC, National Institute for Occupational Safety and Health. July 2002. *Guidance for Controlling Potential Risks to Workers Exposed to Class B Biosolids*.

For organic contaminants, an international study in 2011 stated that research on organic contaminants in biosolids has been undertaken for over 30 years and the increasing body of evidence demonstrates that the majority of compounds studied do not place human health at risk when biosolids are recycled to farmland.⁵ Nevertheless, the study further states, “continued vigilance in assessing the significance and implications of ‘emerging’ [organic contaminants] in sludge is necessary to support and ensure the long-term sustainability and security of the beneficial agricultural route for biosolids management.”

A study using simulation results of biosolids land application activities in 2013 demonstrated that the current regulatory pollutant limits for land-applied biosolids were sufficiently conservative to minimize negative human health impacts associated with the groundwater exposure pathway.⁶ However, in 2017, the U.S. Geological Survey (USGS) and Colorado State University employees published a journal article that found that biosolids runoff containing anthropogenic contaminants (those originating in human activity)—such as antimicrobials, flame-retardants and plasticizers—may pose a potential threat to the environment.⁷ The USGS report found that rainfall can mobilize contaminants from agricultural fields using biosolids directly to surface waters and redistribute them to terrestrial sites away from the point of application. Furthermore, according to this article, the potential for runoff and pollutant mobilization during rainstorms persists even a month after multiple heavy rainfall events.

Law and Regulations

The Clean Water Act § 405(d) sets the framework for biosolids regulations. In 1993, the management of sewage sludge was brought under the 40 CFR Part 503, *Standards for the Use or Disposal of Sewage Sludge* (Biosolids Rule) and the National Pollutant Discharge Elimination System (NPDES) permit program. The EPA published the Biosolids Rule because the Clean Water Act requires the EPA to establish standards for the use and disposal of biosolids to protect public health and the environment from certain pollutants and any reasonably anticipated adverse effect.⁸

The Biosolids Rule establishes standards that consist of general requirements, pollutant limits, management practices, and operational standards for the final use or disposal of biosolids generated during domestic sewage treatment. Standards

⁵ Clarke, B. O. and Smith, S. R. “Review of ‘emerging’ organic contaminants in biosolids and assessment of international research priorities for the agricultural use of biosolids.” *Environment International*. 37(1): 226–247. (2011).

⁶ McFarland, M. J. et al. “Protecting Groundwater Resources at Biosolids Recycling Sites.” *Journal of Environmental Quality* 42(3): 660–665. (2013).

⁷ Gray, James L., Borch, T., Furlong, E.T., Davis, J.G., Yager, T.J., Yang, Y., and Kolpin, D.W. “Rainfall-runoff of anthropogenic waste indicators from agricultural fields applied with municipal biosolids.” *Science of the Total Environment* Vol. 580 (February 2017): 83–89.

⁸ Unlike other waste materials, biosolids applied to land in accordance with the Biosolids Rule is a federally permitted release under the Comprehensive Environmental Response, Compensation, and Liability Act.

include the frequency of monitoring and recordkeeping requirements. Additional details on standards and requirements are in Chapter 2. The Biosolids Rule applies to any person or entity who:

- Prepares sewage sludge.
- Applies sewage sludge to the land.
- Fires sewage sludge in a sewage sludge incinerator.
- Owns/operates a surface disposal site.
- Emits exit gas from a sewage sludge incinerator stack.

The Biosolids Rule at 40 CFR Part 503 governs biosolids, including those applied to the land, and contains limits for pollutants in land-applied biosolids. In



Biosolids forest land application. (EPA photo)

addition, the rule establishes a ceiling concentration for the regulated pollutants and limits for cumulative and annual pollutant loading rates: the cumulative rate is the maximum amount of regulated pollutants that can be applied to an area of land. The annual rate is the maximum amount of a pollutant that can be applied to a unit area of land during a 365-day period. Currently, the Biosolids Rule regulates nine pollutants for land application. Land application must also comply with protections for endangered species, and appropriate precautions must be taken to prevent biosolids applications to frozen, snow-covered or flooded land from entering surface waters or wetlands unless specifically permitted under the Clean Water Act.

In most cases, the preparer of biosolids (usually the owner/operator of a treatment works) will be responsible for sampling the biosolids for metals, pathogens and (where applicable) vector attraction reduction. The land applier is responsible for verifying that the biosolids application does not exceed the agronomic rate,⁹ and identifying the amount of nitrogen needed by the crop or vegetation grown on the land to minimize the amount of nitrogen passing into the ground water.

Biosolids Categories—Class A and Class B

The EPA has two categories of biosolids:

- Class A biosolids undergo more treatment than Class B biosolids, to the point where the concentration of pathogens is reduced to levels low enough so that no additional restrictions or special handling precautions are required by the Biosolids Rule.

⁹ “Agronomic rate is the whole sludge application rate (dry weight basis) designed to: (1) provide the amount of nitrogen needed by the food crop, feed crop, fiber crop, cover crop or vegetation grown on the land; and (2) minimize the amount of nitrogen in the sewage sludge that passes below the root zone of the crop or vegetation grown on the land to the ground water.” 40 CFR §503.11(b).

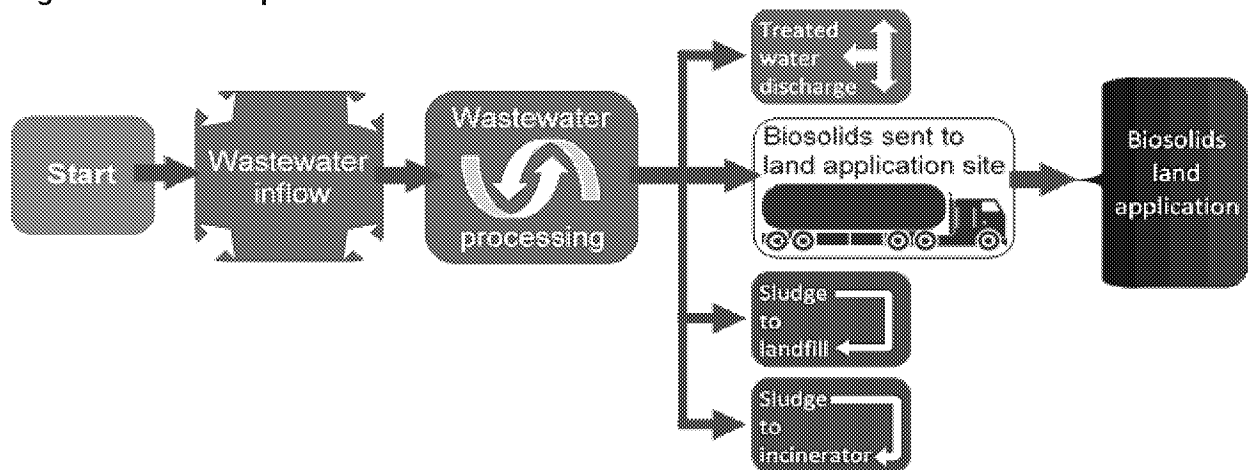
- Class B biosolids treatments reduce but do not eliminate pathogens. For this reason, federal regulations require additional measures to restrict public access and limit livestock grazing for specified time periods after land application of Class B biosolids. This restricted access allows time for the natural die-off of pathogens in the soil. However, the restricted access does not apply to workers involved with the handling and land application of Class B biosolids.

The Biosolids Rule lists the options for meeting pathogen and vector attraction reduction requirements. (Appendix A contains Class A pathogen alternatives.)

Biosolids Processing Steps

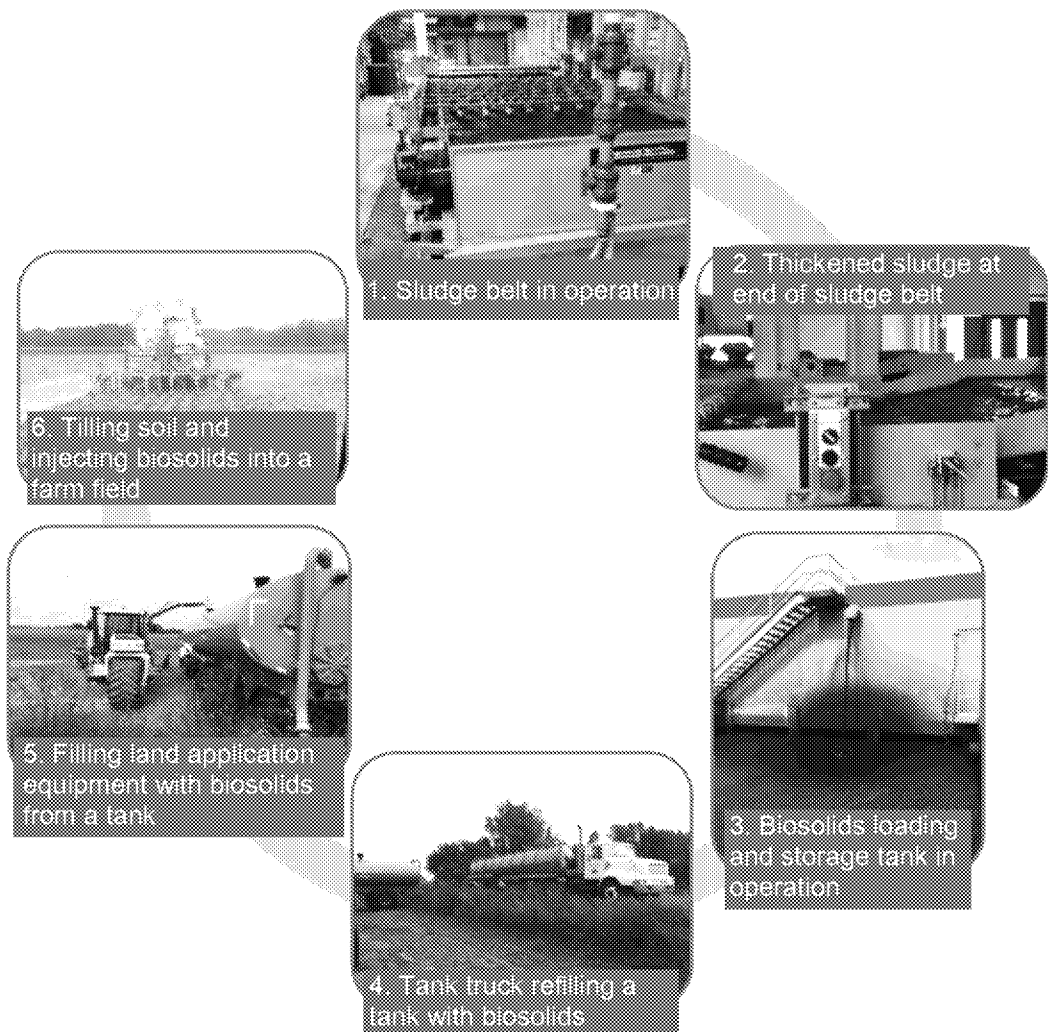
The wastewater treatment plant typically produces liquid, solid or semisolid biosolids material from the residuals of the wastewater treatment process. People who prepare sewage sludge have choices for managing the ultimate fate of biosolids. Treatment plant operators can send biosolids to a landfill or an incinerator. However, if the biosolids meet the regulation requirements, those biosolids may be sent for land application. Properly treated biosolids may be transported by truck to a site where they are applied directly to the land. The biosolids process is shown in Figure 1; land application is shown in Figure 2.

Figure 1: Biosolids process model



Source: Office of Inspector General (OIG)-prepared image.

Figure 2: Steps used to create and apply biosolids to the land



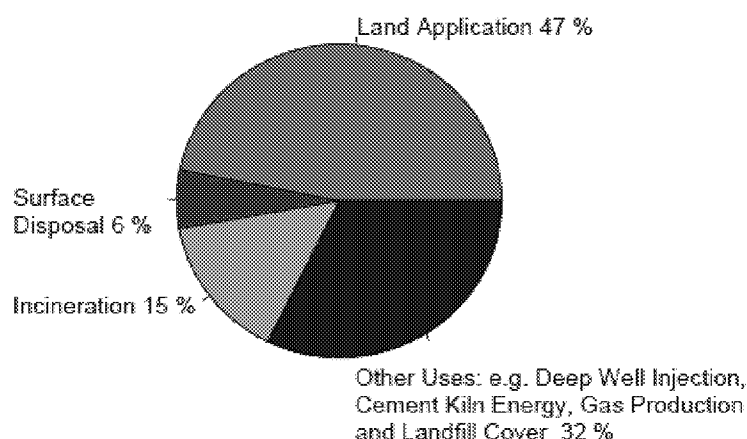
Source: OIG-prepared image.

Biosolids Use

Approximately 47 percent of the biosolids generated in the United States are applied to land to improve and maintain productive soils and stimulate plant growth. The EPA estimates that 7.1 million tons of biosolids were generated for use or disposal in 2000. The EPA referred us to the latest compilation of data available, a 2007 North East Biosolids and Residuals Association report that also stated that 7,180,000 dry tons of biosolids were beneficially used or disposed of in the 50 states in 2004. The agency also referred us to EPA enforcement data,¹⁰ which we used in Figure 3 to show where and how biosolids from major publicly operated treatment works (POTWs) were used in 2016.

¹⁰ EPA enforcement data used came from the EPA's Enforcement and Compliance History Online (known as "ECHO") website, which allows searches by facility to assess compliance with environmental regulations.

Figure 3: Biosolids use from major POTWs—2016



Source: EPA enforcement data.

Biosolids Research on Beneficial Reuse

Biosolids research is being conducted under a committee involving multiple institutions and entities nationwide (e.g., universities, the U.S. Department of Agriculture, the EPA, and municipal governments).¹¹ Committee research includes long-term studies, field studies and laboratory investigations. Research conducted previously by this group formed the basis for the Biosolids Rule. The committee plans to continue investigating the movement and toxicity of trace element and trace organic contaminants in the food chain, and other topics to inform the risk assessments required by the Biosolids Rule.¹²

EPA's Compliance Monitoring and Enforcement for the Biosolids Program

In 2013, the EPA consolidated its oversight of biosolids compliance monitoring and enforcement into the Biosolids Center of Excellence, located in Region 7. The

EPA's Biosolids Program

The EPA Biosolids Program's goal is to protect public health and the environment from any reasonably anticipated adverse effects of regulated pollutants that might be present in biosolids.

Center of Excellence collects and reviews annual biosolids reports from major permit holders and conducts nationwide enforcement and compliance for the federal biosolids program. At the time of our review, there were two staff at the center. They focused on biosolids enforcement for major wastewater treatment facilities that submit biosolids annual reports. In 2017, there were approximately 2,700 of these major facilities. The center staff added that tips and complaints are a source for inspections, and each year they select

¹¹ W3170: Beneficial Reuse of Residuals and Reclaimed Water: Impact on Soil Ecosystem and Human Health.

¹² As described in Chapter 2, the EPA is required to review the biosolids regulations at least every 2 years to determine which, if any, additional pollutants should be regulated. The EPA uses risk assessments to assess the potential risk to human health or the environment associated with exposure to pollutants when biosolids are land applied as fertilizer or soil amendments, disposed on a surface disposal site or incinerated.

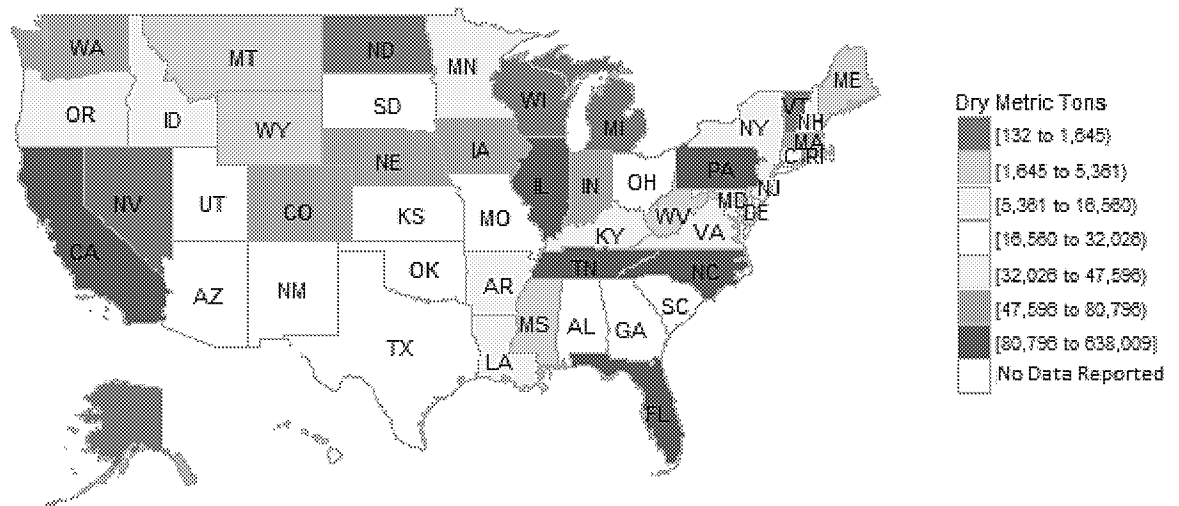
20 percent of the facilities for in-depth annual report reviews based on permit numbers. Using this approach, each facility gets a thorough review once every 5 years. The center staff explained that inspections were de-emphasized due to other, higher-priority water issues. The main focus for the center's two full-time-equivalent employees is reviewing annual reports filed by permittees while also reviewing inspection reports referred to them for compliance.

The EPA has primacy over biosolids programs in 42 states and Indian Country. The EPA authorized eight states to administer their own biosolids programs: Arizona, Michigan, Ohio, Oklahoma, South Dakota, Texas, Utah and Wisconsin.

State Biosolids Program Reporting Requirements

Recently, the EPA implemented an electronic reporting system for biosolids and required all biosolids permit holders to file their 2016 annual reports in the new e-reporting system. The e-reporting system does not currently require reports from the eight authorized states, minor facilities (facilities with design flows less than 1 million gallons per day or serving less than 10,000 people), or facilities otherwise not required to report under the Biosolids Rule. However, by 2020, according to the EPA, the authorized states will submit reports to the electronic system. One state that we interviewed tracks where the biosolids are applied; in other states, the applier or generator tracks where biosolids are applied whereas the EPA only records where the material is generated. Using EPA enforcement data, we created the following map (Figure 4) showing the amount reported by permit holders for their 2016 biosolids generated for application on agricultural land.¹³

Figure 4: Biosolids generated for land application



Source: OIG-created from EPA data.

¹³ In 2016, about 700 facilities did not use the new e-reporting system and filed their reports on paper or by email. Those data are not included in the EPA's enforcement data system.

Responsible Offices

Multiple offices within the EPA perform biosolids-related tasks:

- The Office of Water is responsible for implementing the Clean Water Act. Within the Office of Water, the Office of Science and Technology conducts the biennial biosolids reviews required by Section 405 of the Clean Water Act and provides input for biosolids facility inspection goals, while the Office of Wastewater Management provides technical expertise on biosolids.
- The Office of Land and Emergency Management considers land application as part of the cleanup process for contaminated site remediation. According to the Office of Superfund Remediation and Technology Innovation, it has experience evaluating the use of biosolids for site remediation.
- The Office of Enforcement and Compliance Assurance (OECA) addresses pollution problems that impact American communities—including those related to biosolids—through civil and criminal enforcement.
- The Office of Research and Development, through the National Risk Management Research Laboratory, advances scientific and engineering solutions to manage current and future environmental risks. The laboratory's past research included biosolids applied to a land test site.
- The Region 7 Biosolids Center of Excellence staff collect and review annual biosolids reports and are the national leads for EPA biosolids enforcement activities across the country. The center handles all the data for the annual biosolids reports and any inspections conducted. OECA oversees the center.

Noteworthy Achievements

The Biosolids Rule requires certain biosolids generators to file annual reports each February. Previously, these reports were submitted on paper in a nonstandard format. The NPDES Electronic Reporting Rule (“NPDES eRule”) required electronic filing of reports after December 21, 2016. The EPA stated that for the annual reports due in February 2018, the EPA received 2,226 electronic report submissions and an additional 81 reports submitted on paper or other nonstandard formats—a 96.5 percent electronic submission rate in only the second year for electronic report submissions.

Scope and Methodology

We conducted our performance audit from June 2017 to July 2018, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to

provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

For the purpose of this report, we considered a control to be any law, regulation, guidance, policy or activity that the EPA employs to accomplish the program objectives.

To address our audit objective, we reviewed prior reports (see Appendix B) related to biosolids and information from citizens who contacted us about our work. We obtained information from and interviewed employees within the EPA's Office of Water, Office of Research and Development, Office of Land and Emergency Management, OECA, and Region 7. We obtained other information from, and interviewed staff at, the National Association of Clean Water Agencies, Water Environment and Reuse Foundation, and Arizona State University Institute for Biodesign. We also spoke with state officials from Arizona, California, Illinois, Minnesota and Wisconsin. We interviewed staff, toured and observed operations at the Mount Horeb and Madison Waste Water Treatment Plants and the Madison Metrogro Facility. As shown in the video below, we also observed the land application process at a farm near Madison, Wisconsin.



Tilling soil and injecting biosolids into a farm field near Madison, Wisconsin. Click on the image above or [here](#) to play the OIG video clip. [External link]

We reviewed human health and environmental research related to biosolids land application. We also reviewed the Clean Water Act, regulations and EPA guidance related to sewage sludge, and enforcement actions taken against facilities between 2012 and 2017.

We reviewed Office of Management and Budget memorandums, Office of Management and Budget Circular A-130, the EPA's Open Government Plan, the EPA Enterprise Information Management Policy, and the EPA Mission Statement for guidance on information sharing.

We did not evaluate the information system controls, as those controls were not significant to our audit objective.

Prior Reports

Information on prior OIG reports is in Appendix B.

Chapter 2

EPA Lacks Data Needed to Determine the Safety of Pollutants in Biosolids

The controls over the land application of sewage sludge (biosolids), including laws, regulations, guidance, policies or activities, were incomplete or had weaknesses and may not fully protect human health and the environment. The EPA consistently monitored biosolids for nine regulated pollutants. However, the agency lacked the data or risk assessment tools needed to make a determination on the safety of 352 pollutants found in biosolids. The EPA identified these pollutants in a variety of studies from 1989 through 2015. Our analysis determined that the 352 pollutants include 61 designated as acutely hazardous, hazardous or priority pollutants in other programs. The Clean Water Act requires the EPA to review biosolids regulations at least every 2 years to identify additional pollutants and promulgate regulations for such pollutants. Existing controls are based on the Clean Water Act and the EPA's Biosolids Rule and include:

- Testing for nine pollutants (all heavy metals).
- Researching for additional pollutants that may need regulation.
- Reducing pathogens and the attractiveness of biosolids to flies, mosquitoes and other potential disease-carrying organisms.
- Labeling, including for bagged biosolids sold commercially.
- Conducting compliance monitoring activities at facilities generating biosolids.

However, the EPA has chosen to reduce staff and resources in the biosolids program over time, creating barriers to addressing control weaknesses identified in the program. Past reviews showed that the EPA needed more information to fully examine the health effects and ecological impacts of land-applied biosolids. In these cases where more information is needed but does not exist, the related law and regulations are silent on whether the EPA is required to obtain additional data to complete biosolids risk assessments. Without such data, the agency cannot determine whether biosolids pollutants with incomplete risk assessments are safe. The EPA's website, public documents and biosolids labels do not explain the full spectrum of pollutants in biosolids and the uncertainty regarding their safety. In addition, the EPA has not conducted regular biosolids training, and its inspection goals are different than what the agency recommends for authorized states.

Weaknesses in Health and Environmental Controls over Biosolids

Control weaknesses in the EPA's implementation of laws, regulations, guidance, policies or activities related to the EPA's biosolids program pose a risk to the agency's mission to protect human health and the environment from risks related to the land application of biosolids. The EPA has chosen to deprioritize the biosolids program and staff over time, creating barriers to its ability to address control

weaknesses. For example, around 2012, the EPA shifted some traditional biosolids enforcement resources in OECA¹⁴ to other higher-priority enforcement areas, leaving a minimal presence of two full-time-equivalent employees in the Biosolids Center of Excellence. The Office of Water's Office of Science and Technology staff, tasked with conducting risk assessments for biosolids, stated that the biosolids program was a lower priority for EPA management, resulting in funding and data shortages in addition to a departure of biosolids expertise.

The Clean Water Act and the Biosolids Rule establish standards and regulations for the production, treatment and land application of biosolids. Also, EPA and government policies on transparency help keep the government and regulated community accountable to the public. The biosolids regulations, standards, transparency policies and EPA's mission provide controls to protect human health and the environment from risks associated with the land application of biosolids. By design, many of the controls in the Biosolids Rule are self-implementing, meaning that owner/operators, land appliers and others must comply with the rule even if they have not been issued a permit covering biosolids use. The EPA has identified, but not completed risk assessments on, hundreds of pollutants in biosolids.

Select controls over the land application of biosolids and areas where we identified gaps and control weaknesses are listed in Table 1; details on each control are discussed in the sections that follow.

Table 1: Select control weaknesses and implementation status for land-applied biosolids

Control	Description	EPA Implementing?
Testing	<ul style="list-style-type: none"> Biosolids Rule 40 CFR § 503.13 	Yes
Research	<ul style="list-style-type: none"> Clean Water Act § 405(d)(2)(C) 	Yes, but with control weaknesses
Pathogen and Vector Attraction Reduction Methods	<ul style="list-style-type: none"> Biosolids Rule 40 CFR § 503.15 	Yes, but with control weaknesses
Sharing Information with the Public – EPA Website	<ul style="list-style-type: none"> EPA Mission Statement EPA Open Government Plan EPA Enterprise Information Management Policy Office of Management and Budget Circular A-130 and Memos M-10-06, M-13-13 and M-16-16 on Open Government 	Limited
Sharing Information with the Public – Labeling	<ul style="list-style-type: none"> Biosolids Rule 40 CFR § 503.14 EPA Mission Statement EPA Open Government Plan EPA Enterprise Information Management Policy Office of Management and Budget Circular A-130 and Memos M-10-06, M-13-13 and M-16-16 on Open Government 	Yes, but with control weaknesses
Training	<ul style="list-style-type: none"> Clean Water Act §§ 104(a)(1), 104(g)(1) and 104(g)(3)(C) 	Limited
Compliance Monitoring	<ul style="list-style-type: none"> Clean Water Act NPDES and goals set by EPA 	Yes, but with control weaknesses

Source: OIG analysis.

¹⁴ In August 2012, OECA issued Budget Adjustment Plans summarizing efforts to re-focus resources and staff on problems that have the greatest impact on human health and the environment while reducing spending in other program areas. In that plan, OECA decided to shift resources devoted to traditional biosolids enforcement work to higher-priority enforcement areas.

Control: Testing

EPA Oversees Required Testing for the Nine Regulated Pollutants

Description of control: Those who prepare biosolids for use on the land are required to test for nine heavy metals. This control is self-implemented.

Status: Implementing.

Biosolids materials are tested for pollutants and must be within specified concentration levels, based on regulatory standards and/or ceiling concentration limits for nine heavy metals: arsenic, cadmium, copper, lead, mercury, molybdenum, nickel, selenium and zinc. The EPA and authorized state programs oversee the monitoring of biosolids for these metals and complete an annual review of compliance with established standards for a subset of the major facilities. According to the EPA and other stakeholders interviewed, there have been no reports of cases of significant health or environmental damage resulting from the land application of biosolids. Nevertheless, many of the same stakeholders we spoke with told us that more research is needed to determine whether currently unregulated and emerging pollutants found in biosolids are harmful and should be regulated.

Control: Research

Research Is Needed on over 300 Other Pollutants Found in Biosolids

Description of control: The EPA is required to review the biosolids regulations at least every 2 years, to identify additional pollutants and promulgate regulations for such pollutants. The EPA could, but is not required to, obtain additional information to complete the risk assessments.

Status: Implementing, but with control weaknesses.

Until May 2018, the EPA was not fully implementing requirements in the Clean Water Act to review biosolids regulations. The required 2013 and 2015 biennial reviews were not complete. They were still “under review” and unavailable to the public. It was not until our preliminary findings were shared in March 2018 that the EPA completed these reviews. According to the EPA, the 2017 biennial review should be completed by December 2018.

Existing biosolids data and studies do not fully examine the pollutants found in biosolids, especially unregulated pollutants. Until such research and data exist, the EPA cannot determine if any regulations should be issued. In over 20 years, no new pollutants have been regulated.

Piecing together information from the 2015 biennial biosolids review, the 2001 and 1989 National Sewage Sludge Surveys and other information, the EPA identified 352 pollutants in biosolids. The EPA does not have complete risk assessment information on these pollutants; therefore the agency cannot say, whether the pollutants are safe or unsafe when found in biosolids.

Details on issues related to research follow.

352 Pollutants—Some Hazardous—Found in Biosolids

The EPA and others testing biosolids material have found unregulated and emerging pollutants in biosolids. The EPA's most recent list of pollutants found in biosolids with incomplete risk assessments included 352 pollutants. When present in biosolids material, it is not well established if or how these pollutants are harmful to humans or the environment, or at what level they are harmful.

The EPA identifies unregulated pollutants in biosolids through surveys, which include sampling and testing of biosolids material.¹⁵ Unregulated pollutants identified include pharmaceuticals (e.g., ciprofloxacin, diphenhydramine and triclocarban); steroids and hormones (e.g., campesterol, cholestanol and coprostanol); and flame retardants. The agency also identified perfluoroalkyl substances (PFASs) and perfluorooctanoate (PFOA) in biosolids research.

We took the EPA's list of 352 pollutants without full risk assessment data and compared that list with three other hazardous lists: (a) the Resource Conservation and Recovery Act (RCRA) hazardous waste listings, (b) the EPA priority pollutant list, and (c) the National Institute for Occupational Safety and Health's (NIOSH's) list of hazardous drugs. We found that 61 of the 352 pollutants appeared on one or more of the hazardous lists. According to the EPA, without risk assessments on each chemical, it is unknown whether the pollutants in biosolids are harmful. Of the 352 biosolids pollutants:

- 32 are hazardous wastes under RCRA (four of which are acutely hazardous).
- 35 are EPA priority pollutants.
- 16 are NIOSH hazardous drugs.

The biosolids pollutants without a full risk assessment and the corresponding waste listings are shown in a table in Appendix C.

Data Necessary to Determine Risk Are Unavailable

The EPA lacks the data or risk assessment tools to make a determination on the risk level for the 352 pollutants identified in biosolids. The regulations for biosolids do not require the EPA to obtain the data necessary to complete risk assessments. The tools to perform risk assessments on pollutants found in

¹⁵ The EPA's findings on additional pollutants in biosolids material are in the agency's Sewage Sludge Surveys.

biosolids, according to the EPA, identify pollutants, pathways, (e.g., drinking water ingestion, produce ingestion) and receptors (e.g., adult, child). The results inform decisions about the need to perform more refined risk assessments or address data gaps and uncertainties. If chemicals are found in biosolids that do not pass screening, a multimedia, multi-pathway, multi-receptor, probabilistic risk assessment modeling framework is needed. According to the EPA, data gaps or the lack of risk assessment tools prevent it from completing assessments on the 352 pollutants and determining whether the pollutants pose an acceptable or unacceptable level of risk.

The EPA lacks data on human health and ecological toxicity values (e.g., studies that are adequate for evaluating hazards following acute or chronic exposure to pollutants) as well as other parameters to complete these risk assessments. In the EPA's 2015 biennial review of biosolids (the most currently published review), it stated in the summary that the available data for many of the pollutants identified were not sufficient at that time to evaluate risk using then-current biosolids modeling tools.

**Information Needed for
Biosolids Risk Assessments
Using Current Tools**

- Human health and ecological toxicity values (i.e., studies that are adequate for evaluating hazards following acute or chronic exposure).
- Exposure data and/or physical chemical properties.
- Pollutant concentrations in U.S. biosolids.
- Environmental fate and transport properties. Data on half-life, mobility, and bioaccumulation are needed to model exposure to humans and wildlife.

Source: EPA 2015 biennial review

EPA's Biennial Reviews Take Several Years to Complete

More than 20 years after the Biosolids Rule was finalized, no new pollutants have been added to the list of nine metals regulated under the rule. When we shared our initial findings with the EPA in March 2018, it had not finalized its 2013 and 2015 biennial reviews of the biosolids standards required by the Clean Water Act and was not in compliance with that provision of the act. Until May 2018, when the EPA put the 2013 and 2015 biennial reviews on its website, the required reviews were still "under review" and unavailable to the public.

***EPA Efforts to Identify
Biosolids Pollutants***

For the **biennial review**, the EPA collected and reviewed publicly available information on the occurrence, fate and transport in the environment, human health and ecological effects, and other relevant information for toxic pollutants that may occur in U.S. biosolids.

The EPA's **National Sewage Sludge Surveys** were used to obtain unbiased national estimates of the concentrations of several hundred pollutants in biosolids.

The EPA is required to review the biosolids regulations at least every 2 years to identify additional toxic pollutants and promulgate regulations for such pollutants. This information from biosolids reviews—including an assessment of the potential risk to human health or the environment associated with exposure to pollutants found in biosolids, when data are available—can assist state biosolids program managers and wastewater treatment operators in making decisions on whether to conduct additional pollutant monitoring at local systems. Information such as this can also be used by land owners, concerned community members and

scientific researchers to determine whether and what pollutants have been found in biosolids, and the corresponding risk associated with those pollutants when applying biosolids. The EPA has now completed and published its statutorily-required biennial reviews for 2005–2015; the 2017 biennial review is still under development.

Impact of Pollutants in Biosolids Unknown; Additional Research Needed

Despite the biosolids surveys and biennial reviews, the EPA, other federal agencies and external research studies have not fully examined the effects and impacts of pollutants in biosolids. While there are beneficial uses of biosolids, the absence of research leaves wide gaps for what is known on the health and environmental impacts of biosolids.

The need for additional biosolids research has been raised by many groups and individuals, including a review by the National Academy of Sciences. As a result, the EPA is creating tools that will assist in gathering biosolids information for land application scenarios. These include a probabilistic risk assessment tool and a screening tool. According to the EPA, it does not have a timeline for completion. Nonetheless, states and external stakeholders we spoke with do not believe the currently available research is sufficient. The EPA's Office of Science and Technology staff informed us that their research budget is small and there are no funds to support outside research; there are less than the equivalent of one-and-a-half full-time staff working on biosolids in the Office of Science and Technology.

Gaps in the research conducted by the EPA have resulted in stakeholders—such as the state programs, wastewater treatment plants and industrial groups—working to determine how improvements can be made to the quality of the biosolids produced. One researcher we interviewed shared that for trace pharmaceuticals and chemicals, there are unanswered questions with respect to the long-term effects of those in the environment, while another recommended that studies be conducted to look at the effects and impacts of biosolids over time. There are also concerns that biosolids may be creating antimicrobial-resistant strains of pathogens that can adversely impact human health. In addition, biosolids odor has been a main complaint from the public, according to researchers and EPA and state staff.

While the EPA's Office of Research and Development conducted a field-scale land application study to evaluate sampling methods and analytical techniques for biosolids, both an EPA risk assessor and an academic researcher stressed the need for more long-term studies of biosolids. The academic researcher told us there is a need for long-term epidemiological studies that look at, and geographically track, exposure to pathogens, as well as occupational health studies that look at biosolids applicators compared to a control group. A non-government researcher we spoke with said the studies required to determine long-term aspects of human and environmental health related to biosolids would be costly and labor intensive, and would require an extended period of time to conduct. One stakeholder added that wastewater treatment

plants do not have funding available for biosolids research since they are publicly funded and, as such, have difficulty in getting funds for research.

Control: Pathogen and Vector Attraction Reduction Methods

Unclear Pathogen Reduction and Sampling Methods Lead to Public Health Concerns

Description of control: Operational standards to reduce pathogens and vectors in biosolids apply to those who use or dispose of biosolids, including generators and land-applicators.

Status: Implementing, but with control weaknesses.

The EPA relies on biosolids generators to follow required methods. According to EPA and state managers, additional clarifications or revisions are needed on the pathogen alternatives and guidance for biosolids sampling methods.

In addition to testing for nine regulated metals, biosolids generators and land appliers must closely follow pathogen reduction¹⁶ and sampling methods to reduce health risks and meet regulatory requirements. The EPA's Pathogens Equivalency Committee members said that two of the Class A pathogen reduction alternatives¹⁷—alternatives 3 and 4—should be revisited or eliminated, as it is not clear whether the alternatives are protective of public health. State biosolids staff also said it was unclear whether the alternatives were working and noted the same pathogen reduction alternatives (3 and 4) are not written clearly in the Biosolids Rule.

According to one state biosolids coordinator and our own review, the EPA's guidance documents on biosolids sampling methods for fecal coliform are contradictory. In the EPA's testing method—EPA Method 1681¹⁸—the EPA allows for the averaging of fecal coliform sample results in Class A biosolids using the mean fecal coliform bacterial density of at least seven samples. However, in the EPA's 2003 Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge, it states that “for Class A biosolids, analytical results are not averaged: every sample analyzed must meet the Class A requirements.” Fecal coliforms are used as an indicator organism because reduction in fecal coliforms correlates to the reduction of *Salmonella* and other organisms. Incorrect sampling that masks higher numbers of fecal coliforms can lead to human health issues such as gastrointestinal or other sicknesses caused by exposure to *Escherichia coli*, *Salmonella* and *Shigella*. If not properly treated and managed

¹⁶ For protection against harmful pathogens, biosolids applied to the land must meet either the Biosolids Rule Class A or Class B pathogen reduction requirements. The two classes differ depending on the level of pathogen reduction that has been obtained. See Chapter 1 for a more complete description of the differences.

¹⁷ For Class A there are six options. See Appendix A for more details.

¹⁸ U.S. EPA Method 1681: Fecal Coliforms in Sewage Sludge (Biosolids) by Multiple-Tube Fermentation using A-1 medium, EPA-821-R-06-013. July 2006.

during use as a soil amendment, biosolids can create water quality and public health problems.

In addition to the confusion with the two EPA guidance documents, new technologies to reduce pathogens are now available. These new technologies can be reviewed by the EPA's Pathogens Equivalency Committee but the approval process is lengthy and costly for the biosolids generator or applier. Even without additional rulemaking, the EPA could reduce confusion by clarifying the methods in question and issuing national guidance on what new technologies are allowable options for pathogen reduction.

Control: Sharing Information with the Public - EPA's Public Website

EPA's Public Safety Statement Does Not Disclose Data and Risk Assessment Limitations

Description of control: The EPA's mission statement and other government documents on transparency include ensuring that all parts of society have access to accurate information sufficient to effectively participate in managing human health and environmental risks.

Status: Not fully implemented.

The EPA posts frequently asked questions and answers on biosolids on its public website and makes biennial review summaries available to the public when complete. However, on its website, the EPA's responses to questions and answers on biosolids safety rely on a 2002 National Research Council of the National Academy of Sciences report.¹⁹ On its website, the EPA does not disclose that because it cannot assess the safety of the 352 pollutants found in biosolids, it cannot inform the public as to whether the biosolids are safe. Furthermore, until May 2018, the EPA was not implementing the requirement to review biosolids regulations, and thus the 2013 and 2015 reviews were unavailable to the public.

In the face of data gaps, a lack of risk assessment tools, and uncertainty regarding the safety of biosolids, the EPA is not providing clear and complete information to the public. Concerned citizens are questioning the safety of biosolids, particularly for agricultural land,

Use of Biosolids Can Limit Agricultural Options

Biosolids are applied to land within all 50 U.S. states, including land used for agricultural production. On agricultural lands, growers may face limitations on where and how food may be sold. Some municipalities or counties have voted on ordinances that ban or restrict the use of biosolids. In addition, the U.S. Department of Agriculture banned the use of biosolids in the production and handling of agricultural products that are sold, labeled or represented as organic in 2000. Countries and regions of countries within the European Union have effectively banned agricultural application of biosolids and placed additional restrictions on agriculture.

¹⁹ National Research Council of the National Academy of Sciences. Biosolids Applied to Land: Advancing Standards and Practices. The National Academies Press. 500 Fifth Street NW, Washington, D.C. 20001 (2002).

and some municipalities voted on local ordinances restricting biosolids altogether. The EPA's webpage on biosolids has a section on frequently asked questions about biosolids that includes the question "Are biosolids safe?" EPA scientists currently working on biosolids cannot definitively say whether the pollutants in biosolids are safe without completing the full risk-assessment process on all identified pollutants. However, this constraint is not disclosed on the EPA's public website. Until recently, the EPA, relied on a 1996 National Research Council of the National Academy of Sciences study and told the public:

the use of these materials in the production of crops for human consumption, when practiced in accordance with existing federal guidelines and regulations, presents negligible risk to the consumer, to crop production, and to the environment.²⁰

In July 2018, after the OIG provided initial findings to the agency, the EPA changed its answer to the question of safety to say:

There is no documented scientific evidence that the [Biosolids Rule] has failed to protect public health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids.

The text is from a 2002 National Research Council of the National Academy of Sciences report.²¹

***Biosolids Areas of Concern
Identified by USGS Scientists***

1. When biosolids are land applied as fertilizers, the potential exists for commonly used chemicals (including fragrances, detergents, fire retardants, plasticizers and antibacterials) to run off the land surface into local surface waters.
2. Hormones from biosolids applied to fields may be present in rainfall runoff at concentrations that are high enough to impact the health of aquatic organisms if the runoff reaches streams. Low part-per-trillion concentrations of these chemicals have caused endocrine disruption in aquatic organisms.
3. Chemicals that we commonly use are transferred from our homes to wastewater treatment plants and subsequently transported in biosolids to agricultural fields as soil amendments.

Although the EPA updated its website, it does not elaborate on the additional scientific work needed and without it the 352 pollutants identified in biosolids are not, and cannot yet, be regulated. The EPA lacks the data or risk assessment tools necessary to make a regulatory determination. Therefore, it cannot determine the level at which these pollutants are safe in biosolids.

More recently, USGS scientists and other researchers identified organic chemicals in biosolids. They also found that biosolids contained relatively high concentrations of the active ingredients commonly found in pharmaceuticals as well as other emerging

²⁰ National Research Council of the National Academy of Sciences. Use of Reclaimed Water and Sludge in Food Crop Production. (Washington, D.C.: The National Academies Press, 1996).

²¹ National Research Council of the National Academy of Sciences. Biosolids Applied to Land: Advancing Standards and Practices. The National Academies Press. 500 Fifth Street, NW Washington, D.C. 20001 (2002).

chemicals. A prior OIG report (see Appendix B) found that sewage treatment plants may not be adequately testing for or treating wastewater entering their facilities and are at risk of discharging hazardous chemicals. The EPA is aware of this information and that harmful unregulated pollutants could end up in biosolids. However, the EPA's website response to the question "Are biosolids safe?" does not present this information.

The EPA, as a federal agency, has a responsibility to provide the public with the most accurate information it has available in a format that the public can understand—even if that means providing details on what it does and does not know about the safety of biosolids. The Office of Management and Budget Circular A-130 and multiple memorandums²² provide instructions to federal agencies to make information available to the public. The EPA Open Government Plan and Enterprise Information Management Policy echo these open government principles. Moreover, the EPA's own mission statement includes a provision to ensure that "All parts of society—communities, individuals, businesses, and state, local and tribal governments—have access to accurate information sufficient to effectively participate in managing human health and environmental risks."

Control: Sharing Information with the Public - Labeling

Biosolids Labels Are Not Required to Disclose Additional Pollutants of Potential Risk to Users

Description of control: Labeling requirements apply to those who prepare biosolids for use. Either a label shall be put on the biosolids container that is sold or given away for application to the land, or an information sheet shall be provided to the person who receives the biosolids that are sold or given away.

Status: Implementing but with control weaknesses

Similar to the EPA's website, the EPA's risk communication regarding biosolids should also be transparent. The labeling requirements for biosolids products used in land application are not comprehensive or complete when it comes to listing the presence of pollutants. As a result, consumers are unable to make an informed decision about the use or purchase of biosolids. The Biosolids Rule requires that either a label be put on the biosolids container sold or given away for application to the land, or an information sheet be provided to the person who receives the biosolids sold or given away. The biosolids label or information sheet shall contain the following information:

- The name and address of the person who prepared the biosolids.
- A statement that application of the biosolids to the land is prohibited except in accordance with instructions on the label or information sheet.

²² Office of Management and Budget Memorandums M-10-06, M-13-13 and M-16-16.

- The annual whole biosolids application rate for the biosolids that does not cause any of the annual pollutant loading rates of heavy metals to be exceeded.

However, if the biosolids that are to be sold or given away in a bag or container for land application meet certain pollutant, pathogen and vector attraction reduction requirements, even these labeling requirements do not apply.

Furthermore, not included in the requirements is a list or disclosure of the presence of unregulated pollutants found in biosolids. Also absent is an acknowledgement of the data shortcomings and limitations the EPA faces when assessing the risk of hundreds of pollutants found in biosolids. Some of the pollutants not included in the labeling requirement are pollutants that are regulated by states, other countries, or even other regulatory programs in the United States. Those who buy or are given biosolids may not be aware that potentially harmful pollutants not regulated by the EPA may be present in the material. Without additional labeling requirements to achieve transparency, there is no way for land applicators or community members seeking a source of fertilizer for home gardening to know this information so they can make informed decisions when purchasing the biosolids products.

Flame Retardant Chemicals Have Been Found in Biosolids

Studies indicate that exposure to certain flame retardant chemicals may be associated with a range of health effects, including reduced IQ, learning disorders, cancer, thyroid disruption and reduced fertility. While flame retardants are not regulated in biosolids, many states have regulated or banned the sale of children's products and residential furniture that contain one or more type of chemical flame retardant. California law requires that products sold within the state warn whether they contain any added flame retardants.

Control: Training

EPA Is Not Conducting Biosolids Training in Accordance with the Clean Water Act

Description of control: Congress established a requirement in the Clean Water Act for the EPA to conduct training relating to the causes, effects, extent, prevention, reduction and elimination of pollution. We interpret this to include training on how best to implement the laws, rules and regulations for biosolids land application.

Status: Not fully implementing.

The EPA is not implementing Clean Water Act requirements to conduct training²³ as they apply to: (1) the biosolids program; and (2) the training and retraining of those involved in the operation and maintenance of treatment works and related activities, including biosolids. Although the EPA recently trained biosolids permit holders on how to file electronic annual reports and educated EPA inspectors, the EPA has conducted few technical trainings and has not held conferences for state

²³ Training requirements are under Clean Water Act §§ 104(a)(1), 104(g)(1) and 104(g)(3)(C).

and federal biosolids program managers and coordinators since at least 2011. State program managers we spoke with do not believe the amount and type of training provided by the EPA is sufficient. Training is critical in a self-implementing program, especially considering large staff turnover at the state and regional levels. According to EPA and state staff interviewed, one impact of the reduced training is differing interpretations of the Biosolids Rule.

Periodic training and education would also help regional and state staff consistently understand and implement the Biosolids Rule nationwide. In addition, it could increase efficiency and effectiveness of state programs that, in the absence of EPA training, have to either conduct their own training, find nongovernmental training programs, or go without. This can be costly and there is no certainty that the training is consistent with the EPA's interpretation of the rule. Without the EPA's national conference training, the states have to contact each other for information, therefore receiving the state perspective and not the national perspective on implementing the biosolids program. There is no means for stakeholders to obtain information through EPA-led discussions and there is no web-based repository of technical questions and answers.

Control: Compliance Monitoring

EPA and States Have Inconsistent Compliance Monitoring Goals and Methods

Description of control: The EPA uses the Clean Water Act NPDES Compliance Monitoring Strategy to establish inspection and assessment goals for the authorized states and the EPA biosolids program.

Status: Implementing, but with control weaknesses.

Using flexibility within the EPA compliance monitoring strategy, the agency is able to meet its compliance monitoring goals by conducting desk audits (file reviews), rather than inspections, based on the EPA's Biosolids Center of Excellence plans and protocols. However, we noted control weaknesses.

The EPA and states with biosolids program authorization have inconsistent compliance monitoring goals and inconsistent conditions for the use of desk audits. The compliance monitoring goal and use of desk audits are more stringent for authorized states. As a result, unauthorized states may be deterred from seeking authorization for the biosolids programs. Furthermore, the inconsistent oversight could provide unequal environmental benefits to the public.

The EPA set a goal in the Clean Water Act NPDES Compliance Monitoring Strategy for authorized states to conduct an on-site biosolids inspection of each POTW every 5 years. That goal allows some flexibility to substitute desk audits in lieu of the on-site inspection for certain conditions in states where the EPA is the permitting authority for biosolids. The Compliance Monitoring Strategy states that EPA compliance monitoring will be conducted "in accordance with plans and

protocols established by the EPA Biosolids Center for Excellence.” Those plans and protocols, described in an internal planning document, include a review of approximately 20 percent of the annual reports submitted by major facilities each year. Therefore, over a 5-year period, each major facility should have its annual report reviewed at least once.

The EPA is not required to conduct on-site biosolids inspections per EPA policy. Differences between inspection goals and desk audits for the EPA and authorized state biosolids compliance monitoring are shown in Table 2 below.

Table 2: Compliance Monitoring: Differences between EPA and authorized state biosolids inspections goals and desk audits

	Inspections goal	Desk audits
EPA biosolids program	No specific requirement for inspections; rather, compliance monitoring activities for biosolids facilities will be conducted in accordance with plans and protocols established by the EPA Biosolids Center of Excellence. Site visits [inspections] will be limited to the extent possible.	Conducting a thorough desk audit review of approximately 20 percent of the annual reports submitted by major facilities. Thus, over a 5-year period, each major facility should have their annual report reviewed at least once.
States with authorized biosolids programs	Recommended inspection frequency goal is at least one biosolids inspection of each major POTW every 5 years.	States may substitute an off-site desk audit for biosolids generation, use, and disposal sites that meet the following criteria: <ol style="list-style-type: none"> 1. Not currently subject to enforcement actions or compliance schedules that are the result of concluded enforcement actions. 2. Not been reported in Significant Noncompliance within the previous four quarters. 3. No unresolved single event violation(s) identified in prior inspection(s). 4. No discharge to Clean Water Act Section 303(d) listed waters for pollutant(s) contributing to the listing. 5. No known potential to impact drinking water supplies.

Source: OIG-created table using the EPA's Compliance Monitoring Strategy and EPA Biosolids Center of Excellence Draft Implementation Plan.

Annual reports include information on metals, pathogens and noncompliance issues with reporting biosolids facilities through the use of checkboxes on the annual report. However, if pollutant exceedances take place early in the reporting year, it would take months for the EPA to detect compliance issues. Annual reports also include the amount of biosolids generated. While some states track additional parameters, the federal biosolids program does not include where or how much biosolids were land-applied. The federal biosolids program also does not collect data on the type of land the biosolids were applied to, such as agricultural (i.e., food for human consumption, livestock feed or cover crops) or

residential settings, nor is data collected on how much was applied to each different type of land use.

Further, the EPA may not be effectively recording the biosolids inspection activities that occur during NPDES facility inspections. According to EPA data, the agency has only inspected for biosolids in about one in four major facilities in a 5½-year period. Specifically, the EPA completed 951 biosolids inspections at major facilities out of a total of 3,732 over a 5½-year period ending July 31, 2017. However, according to the Biosolids Center of Excellence and OECA staff, this number of inspections does not include the inspections that may have taken place as part of an NPDES facility inspection. The staff did not believe this information was consistently entered in the electronic system used to report NPDES facility inspection results.

Conclusions

We found that the EPA, depending on the control area, is either not fully implementing its processes, the Clean Water Act and the EPA's Biosolids Rule, or it has control weaknesses. The EPA, through its biennial review of the biosolids regulations, is working to assess the safety of several hundred pollutants found in biosolids but, for the most part, it has not done so. The EPA says it lacks the data and tools necessary to assess the health and environmental risks of many of these pollutants, resulting in the EPA being unable to state whether and at what level the pollutants found in biosolids pose a risk. In these cases, the EPA could—but is not required to—obtain the data. In addition, there are no time limits on completing risk assessments for the pollutants identified in biosolids.

Despite the data and control weaknesses, the EPA implies that, when used correctly, biosolids are safe. The EPA does not disclose the shortcomings of information used to assess safety, nor does it reveal that potentially harmful and unregulated pollutants are present in biosolids such as pharmaceuticals, steroids and flame retardants. EPA scientists working on biosolids told us that without completing risk assessments on all of the pollutants found in biosolids they cannot say whether biosolids are safe. Also, while the number of unregulated pollutants has expanded over time, the EPA has reduced its biosolids program.

Congress directed the EPA to develop and administer the regulations for biosolids. Over time the EPA has reduced the control activities over the biosolids program, including reductions in inspections and training intended to check for regulatory compliance and protect public health and the environment. Without increased nationwide guidance from the EPA on land-applied biosolids, data gaps and the lack of risk assessment tools could persist. In addition, the efficiency and effectiveness of the EPA's work with state programs and protections over human and environmental health may suffer. With the current control weaknesses identified, the biosolids program is at risk of not achieving its goal to protect public health and the environment.

Recommendations

We recommend that the Assistant Administrator for Water and the Assistant Administrator for Enforcement and Compliance Assurance:

1. Utilizing existing tools and capabilities, implement a method or approach to better capture and analyze biosolids inspections data in the EPA's data system of record for any biosolids inspection activities that are conducted during the National Pollutant Discharge Elimination System permit inspections.
2. Establish a nationally consistent and measurable goal for biosolids inspections and nationally consistent desk audit requirements that apply equally to the EPA and authorized states.

We recommend that the Assistant Administrator for Water:

3. Complete development of the probabilistic risk assessment tool and screening tool for biosolids land application scenarios.
4. Develop and implement a plan to obtain the additional data needed to complete risk assessments and finalize safety determinations on the 352 identified pollutants in biosolids and promulgate regulations as needed.
5. Complete and publish all future biosolids biennial reviews, including the 2017 biennial review, prior to the next review required by the Clean Water Act.
6. Publish guidance on the methods for the biosolids pathogen alternatives 3 and 4.
7. Issue guidance on what new technologies are allowable options or alternatives for biosolids pathogen reduction.
8. Issue updated and consistent guidance on biosolids fecal coliform sampling practices.
9. Change the website response to the question "Are biosolids safe?" to include that the EPA cannot make a determination on the safety of biosolids because there are unregulated pollutants found in the biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.

10. Modify the EPA's website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question "Are biosolids safe?" These changes should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.
11. Determine whether the impact on the safety and protection of human health justifies a requirement to include a general disclaimer message on the biosolids labels and information sheets regarding unregulated pollutants and a referral to the website for additional information. Publish the rationale for the determination on the EPA biosolids website.
12. Conduct regular biosolids training and conference calls or meetings for regional and state staff and wastewater treatment operators to improve consistency in rule interpretation and aid in knowledge transfer.
13. In addition to EPA technical biosolids trainings or conferences, start and maintain a website repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.

Agency Response and OIG Evaluation

The EPA provided a written response to our draft report dated September 4, 2018. The agency concurred with the intent of, or partially concurred with, two draft report recommendations (1 and 2) and concurred with seven draft report recommendations (3, 4, 6, 7, 9, 10 and 13). The agency disagreed with five draft report recommendations (5, 8, 11, 12 and 14). Further, for three of the draft report recommendations (4, 10 and 13) the agency agreed with, the initial planned corrective actions did not satisfy the intent of the recommendations.

The OIG met with representatives of OECA on September 6, 2018, and of the Office of Water on September 17, 2018, regarding the agency's response to the recommendations. After these meetings, Recommendations 1 and 14 were slightly modified and Recommendation 12 was rewritten; they were all shared with the agency. Recommendation 5 was removed because we believe the actions taken to address Recommendations 3, 4 and 11 will be responsive to our underlying concerns about the absence of data and research studies needed to determine the level of risk for unregulated pollutants found in biosolids. Therefore, we renumbered the recommendations in this final report, as shown in Table 3.

Table 3: Recommendation numbering changes

Original number	New number
1	1, Modified
2	2
3	3
4	4
5	Removed
6	5
7	6
8	7
9	8
10	9
11	10
12	11, Rewritten
13	12
14	13, Modified

Source: OIG-prepared.

Appendix D provides the full text of the agency's response.

Appendix E provides the revised OIG recommendations and revised agency planned corrective actions.

For Recommendation 1, the agency stated it agreed with the intent but did not clearly state whether it agreed or disagreed with the recommendation. During discussions, OECA explained that a method was already in place that can capture the biosolids inspections data. The OIG slightly modified the recommendation and received a supplemental email from OECA agreeing to the modified recommendation. The agency's planned corrective actions and completion date satisfied the intent of the modified recommendation. This recommendation is resolved with corrective actions pending.

For Recommendation 2, the agency initially agreed in part with the recommendation. Subsequently, the EPA provided email clarification that it agreed with the recommendation and included revised planned corrective actions and a completion date that satisfy the intent of the recommendation. The recommendation is resolved with corrective actions pending.

For Recommendation 3, the agency agreed with the recommendation and offered an acceptable corrective action but did not provide a specific completion date. After our meeting on September 17, 2018, the Office of Water provided an acceptable completion date. This recommendation is resolved with corrective actions pending.

For Recommendation 4, the EPA agreed with this recommendation. The initial corrective action did not fully address the intent of the recommendation. After our meeting on September 17, 2018, the EPA provided acceptable corrective actions and a planned completion date. In addition to the EPA's work on improving the biennial review process, the Office of Water established a performance measure for biennial reviews. This recommendation is resolved with corrective actions pending.

For Recommendation 5, the agency agreed with the recommendation and provided acceptable corrective actions and a planned completion date. This recommendation is resolved with corrective actions pending.

For Recommendation 6, the agency agreed to this recommendation and offered an acceptable corrective action, but it did not provide a specific completion date. Subsequently, the Office of Water provided an acceptable completion date. This recommendation is resolved with corrective actions pending.

For Recommendation 7, the agency did not agree with the recommendation, nor did it provide a corrective action. Therefore, the recommendation is unresolved with resolution efforts in progress.

For Recommendation 8, the agency agreed to this recommendation and offered an acceptable, corrective action, but it did not provide a specific completion date. On September 11, 2018, the Office of Water provided an acceptable completion date. This recommendation is resolved with corrective actions pending.

For Recommendation 9, the agency agreed with this recommendation but did not provide an acceptable corrective action. After our meeting on September 17, 2018, it provided a revised corrective action and date. However, the new corrective action was also not acceptable. The corrective action did not specify that the updates to the EPA's website response to the question "Are biosolids safe?" would include that the EPA cannot make a determination on the safety of biosolids because there are several unregulated pollutants found in biosolids that still need to have risk assessments completed and that the changes to the website would stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids. Therefore, this recommendation is unresolved with resolution efforts in progress.

For Recommendation 10, the agency did not agree with the recommendation and did not offer an alternative corrective action plan to modify the EPA website responding to public questions on the safety of biosolids in the manner requested. After our meeting on September 17, 2018, the EPA did not provide alternative corrective actions. Therefore, the recommendation is unresolved and with resolution efforts in progress.

For Recommendation 11, the agency did not agree with the recommendation and did not offer an alternative corrective action. It believes that issuing guidance on including the EPA website as part of the required biosolids label or information sheets would go beyond what is allowed under the Biosolids Rule. We revised the recommendation to have the EPA determine whether the impact on the safety and protection of human health justifies a requirement to include a disclaimer message on the biosolids label and information sheets. The EPA did not agree with the revised recommendation and stated that it cannot add a new requirement for biosolids labels or sheets without a regulation change. According to the EPA, publishing a rationale on EPA's website for changing (or for not changing) a regulation without a public process would be a violation of the Administrative Procedure Act. The OIG is not recommending that the agency circumvent the rulemaking process, nor is the OIG recommending that the agency impose additional labeling requirements on regulated entities in the absence of a rulemaking. The intent behind the OIG's recommendation is that the agency study whether the risk to human health and the environment is sufficient to warrant undertaking a rulemaking to propose adding additional labeling and/or information sheet requirements, and that the agency publish its rationale on its website. This recommendation is unresolved with resolution efforts in progress.

For Recommendation 12, the agency agreed with the recommendation but the response did not address the training aspect of the recommendation. After our meeting on September 17, 2018, the EPA provided acceptable corrective actions and a planned completion date. This recommendation is resolved with corrective actions pending.

For Recommendation 13, the agency disagreed with the original recommendation, and provided no alternative corrective actions to start and maintain on the EPA website a repository of technical and procedural information as well as general questions and answers. Therefore, the recommendation is unresolved with resolution efforts in progress.

We made changes to this report to address the agency's technical comments where appropriate. The OIG also included in the report additional research studies and other text that describe the beneficial uses of biosolids.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
1	26	Utilizing existing tools and capabilities, implement a method or approach to better capture and analyze biosolids inspections data in the EPA's data system of record for any biosolids inspection activities that are conducted during the National Pollutant Discharge Elimination System permit inspections.	R	Assistant Administrator for Water and Assistant Administrator for Enforcement and Compliance Assurance	6/30/19	
2	26	Establish a nationally consistent and measurable goal for biosolids inspections and nationally consistent desk audit requirements that apply equally to the EPA and authorized states.	R	Assistant Administrator for Water and Assistant Administrator for Enforcement and Compliance Assurance	3/31/19	
3	26	Complete development of the probabilistic risk assessment tool and screening tool for biosolids land application scenarios.	R	Assistant Administrator for Water	12/31/21	
4	26	Develop and implement a plan to obtain the additional data needed to complete risk assessments and finalize safety determinations on the 352 identified pollutants in biosolids and promulgate regulations as needed.	R	Assistant Administrator for Water	12/31/22	
5	26	Complete and publish all future biosolids biennial reviews, including the 2017 biennial review, prior to the next review required by the Clean Water Act.	R	Assistant Administrator for Water	12/31/18	
6	26	Publish guidance on the methods for the biosolids pathogen alternatives 3 and 4.	R	Assistant Administrator for Water	12/31/20	
7	26	Issue guidance on what new technologies are allowable options or alternatives for biosolids pathogen reduction.	U	Assistant Administrator for Water		
8	26	Issue updated and consistent guidance on biosolids fecal coliform sampling practices.	R	Assistant Administrator for Water	12/31/20	
9	26	Change the website response to the question "Are biosolids safe?" to include that the EPA cannot make a determination on the safety of biosolids because there are unregulated pollutants found in the biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	U	Assistant Administrator for Water		
10	27	Modify the EPA's website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question "Are biosolids safe?" These changes should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	U	Assistant Administrator for Water		
11	27	Determine whether the impact on the safety and protection of human health justifies a requirement to include a general disclaimer message on the biosolids labels and information sheets regarding unregulated pollutants and a referral to the website for additional information. Publish the rationale for the determination on the EPA biosolids website.	U	Assistant Administrator for Water		

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status ¹	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
12	27	Conduct regular biosolids training and conference calls or meetings for regional and state staff and wastewater treatment operators to improve consistency in rule interpretation and aid in knowledge transfer.	R	Assistant Administrator for Water	12/31/19	
13	27	In addition to EPA technical biosolids trainings or conferences, start and maintain a website repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.	U	Assistant Administrator for Water		

¹ C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

Class A Pathogen Reduction Requirements

EPA's Summary of Class A pathogen reduction alternatives for biosolids

1. Biosolids must be subjected to one of four time-temperature regimes.
2. Biosolids must meet specific pH, temperature and air-drying requirements.
3. Demonstrate that the process can reduce enteric viruses and viable helminth ova. Maintain operating conditions used in the demonstration after pathogen reduction demonstration is completed.
4. Biosolids must be tested for pathogens--Salmonella sp. or fecal coliform bacteria, enteric viruses, and viable helminth ova--at the time the biosolids are used or disposed, or, in certain situations, prepared for use or disposal.
5. Biosolids must be treated in one of the Processes to Further Reduce Pathogens.
6. Biosolids must be treated in a process equivalent to one of the Processes to Further Reduce Pathogens, as determined by the permitting authority.

Source: The EPA.

Prior OIG Reports

Report No. 2000-P-10, *Biosolids Management and Enforcement*, issued March 20, 2000

We found that the EPA does not have an effective program for ensuring compliance with the land application requirements of 40 CFR Part 503. Accordingly, while the EPA promotes land application, the EPA cannot assure the public that current land application practices are protective of human health and the environment. The OIG recommended that the EPA provide an analysis of whether the agency's proposed actions provide a sufficient basis for assessing compliance with Part 503 and assuring the public of the protectiveness of land application practices. The EPA completed all corrective actions.

Report No. 2002-S-000004, *Status Report: Land Application of Biosolids*, issued March 28, 2002

We reviewed allegations from the National Whistleblower Center concerning the EPA's conduct regarding regulating biosolids and provided a status report on the land application of biosolids. The report examined the following issues: EPA and state staff, the delegation of biosolids programs to states, land application data for seven states, how the EPA responds to and tracks health complaints, risk assessment and pathogen testing concerns, the EPA's relationship with the Water Environment Federation, and public acceptance concerns. We did not make any recommendations.

Report No. 12-P-0508, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal*, issued May 25, 2012

We found that the EPA had not used its RCRA authority to determine whether pharmaceuticals may qualify as hazardous waste. The EPA also did not establish a process for the regular identification and review of pharmaceuticals that may qualify for regulation as hazardous waste. Without a regular process, the EPA cannot provide assurance that pharmaceuticals that may pose a hazardous risk to human health and the environment have been identified. The OIG recommended that the EPA establish a process to review pharmaceuticals for regulation as hazardous waste and develop an outreach and compliance assistance plan for health care facilities managing hazardous waste pharmaceuticals. The EPA completed all corrective actions.

Report No. 14-P-0363, *More Action Is Needed to Protect Water Resources From Unmonitored Hazardous Chemicals*, issued September 29, 2014

We found that management controls put in place by the EPA to regulate and control hazardous chemical discharges from sewage treatment plants to water resources had limited effectiveness. The EPA regulates hazardous chemical discharges to and from sewage treatment plants, but these regulations were not effective in controlling the discharge of hundreds of hazardous chemicals to surface waters such as lakes and streams. Sewage treatment plant staff did not monitor for hazardous chemicals discharged by industrial users. The OIG recommended that the EPA develop a format for sharing annual Toxics Release Inventory data, develop a list of chemicals beyond the priority pollutants list for inclusion in permits, confirm compliance with the hazardous waste notification requirement, and track required submittals of toxicity tests and violations. The EPA completed all corrective actions.

Source: Prior EPA OIG reports.

Unassessed Biosolids Pollutants Categorized as Hazardous or Toxic in Other Federal Programs

The EPA provided us with information to compile a list of 352 unassessed biosolids pollutants using the 2015 biennial review, the 2001 and 1989 National Sewage Sludge Surveys, and other information. According to the EPA, without risk assessments on each chemical, it is unknown whether the pollutants in biosolids are harmful. When we compared the 352 pollutants to the RCRA hazardous waste listings, the EPA priority pollutant list, and the NIOSH list of hazardous drugs, we found that 61 pollutants appeared on one or more of those lists:

- 32 are hazardous wastes under RCRA.
- 35 are on the EPA priority pollutant list.
- 16 are classified as hazardous drugs by NIOSH.

Some of the pollutants were listed under multiple categories. Those pollutants and the corresponding categories we identified are shown in Table C-1.

The 61 pollutants in Table C-1 are designated as hazardous or toxic through other laws, regulations or other government agencies. These entities identify chemicals, drugs and pollutants that are noteworthy due to their hazardous characteristics. For example, RCRA identifies solid wastes that are hazardous. RCRA states that wastes can be hazardous if they exhibit properties such as ignitability, corrosivity, reactivity or toxicity; or because the EPA has determined them to pose a substantial present or potential hazard to the environment or human health when improperly treated, stored, transported, disposed of or otherwise managed.

Of the four lists that RCRA uses for hazardous waste categories, we looked at the “P” (acutely hazardous) and “U” (toxic) lists. The priority pollutant list is a list of 126 pollutants that the EPA regulates under the Clean Water Act and for which the EPA has published analytical test methods. NIOSH has also published a list of drugs considered hazardous because of carcinogenicity,²⁴ teratogenicity²⁵ or other developmental toxicity, reproductive toxicity, organ toxicity (at low doses), genotoxicity,²⁶ or because the structure and toxicity profiles of new drugs mimic existing hazardous drugs. The appearance of any pollutants in biosolids that are also listed on any of the above lists may be a cause for concern.

²⁴ The ability of a substance or mixture of substances to induce cancer or increase its incidence.

²⁵ The ability of a substance to cause permanent structural change that may adversely affect survival, development or function.

²⁶ The ability of a substance to alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with the normal replication processes, or which in a non-physiological manner (temporarily) alter its replication.

Table C-1. List of unassessed pollutants found in biosolids that appear on a hazardous or priority pollutant list

Pollutant	Chemical Abstracts Service Registry Number	Category	RCRA Hazardous Waste - Acutely Hazardous (P) or Toxic (U) List Number	Priority-Pollutant List X = on the list	NIOSH Hazardous Drugs List X = on the list
2,3,7,8 TETRACHLORODIBENZO-P-DIOXIN	1746-01-6			X	
2-Propanone	67-64-1		U002		
Antimony	7440-36-0	Metals		X	
Benz(a)anthracene	56-55-3	PAHs	U018	X	
Benzo(a)pyrene	50-32-8	PAHs	U022	X	
Benzo(b)fluoranthene	205-99-2	PAHs		X	
Benzo(k)fluoranthene	207-08-9	PAHs		X	
Beryllium	7440-41-7	Metals	P015	X	
Bis (2-ethylhexyl) phthalate	117-81-7	SVOCs	U028	X	
Carbamazepine	298-46-4	Other drugs			X
Carbon tetrachloride	56-23-5	Organics	U211	X	
Chloroaniline, 4-	106-47-8	SVOCs	P024		
Chloroform	67-66-3	Organics	U044	X	
Chloronaphthalene, 2-	91-58-7	Organics	U047	X	
Cresol, p- (4-methylphenol)	106-44-5	Preservative	U052		
Chrysene	218-01-9	PAHs	U050	X	
Cyanide	57-12-5	Organics		X	
Cyclophosphamide	50-18-0	Other drugs	U058		X
Dichlorobenzene, 1,3-	541-73-1	Pesticides	U071	X	
Dichlorobenzene, 1,4-	106-46-7	Pesticides	U072	X	
Dimethoate	60-51-5	Pesticides	P044		
Dimethyl phthalate	131-11-3	Organics	U102	X	
Di-n-butyl phthalate (Butoxyphosphate ethanol, 2-)	84-74-2	Plasticizers	U069	X	
Di-n-octyl phthalate	117-84-0	Organics	U107	X	
Endosulfan, α	959-98-8	Pesticides		X	
Endosulfan, β	33213-65-9	Pesticides		X	
Estradiol, 17 α -	57-91-0	Hormones			X
Estradiol, 17 β -	50-28-2	Hormones			X
Estradiol-3-benzoate, β -	50-50-0	Hormones			X
Estriol (estradiol)	50-27-1	Hormones			X
Estrone	53-16-7	Hormones			X
Ethylbenzene	100-41-4	Organics		X	
Ethynyl estradiol, 17 α -	57-63-6	Hormones			X
Fluoranthene	206-44-0	PAHs	U120	X	

Pollutant	Chemical Abstracts Service Registry Number	Category	RCRA Hazardous Waste - Acutely Hazardous (P) or Toxic (U) List Number	Priority-Pollutant List X = on the list	NIOSH Hazardous Drugs List X = on the list
Heptachlor epoxide	1024-57-3	Pesticides		X	
Mestranol	72-33-3	Other drugs			X
Methylene Chloride	75-09-2		U080	X	
Napthalene	91-20-3	PAHs	U165	X	
Nitrophenol, p-	100-02-7	Organics	U170	X	
N-nitrosodibutylamine (NDBA) 924-16-3	924-16-3	Nitrosamines	U172		
N-nitrosodiethylamine (NDEA) 55-18-5	55-18-5	Nitrosamines	U174		
N-nitrosodimethylamine (NDMA) 62-75-9	62-75-9	Nitrosamines	P082	X	
N-nitroso-di-n-propylamine (NDPA) 621-64-7	621-64-7	Nitrosamines	U111	X	
N-nitrosodiphenylamine (NDPhA) 86-30-6	86-30-6	Nitrosamines		X	
N-nitrosopiperidine (NPIP) 100-75-4	100-75-4	Nitrosamines	U179		
N-nitrosopyrrolidine (NPYR) 930-55-2	930-55-2	Nitrosamines	U180		
Norethindrone (norethisterone)	68-22-4	Hormones			X
Norgestimate	35189-28-7	Other drugs			X
Norgestrel (levonorgestrel)	797-63-7	Hormones			X
Pentachloronitrobenzene	82-68-8	Pesticides	U185		
Phenanthrene	85-01-8	PAHs		X	
Progesterone	57-83-0	Hormones			X
Pyrene	129-00-0	PAHs		X	
Silver	7440-22-4	Metals		X	
Sodium valproate	1069-66-5	Other drugs			X
Testosterone	58-22-0	Hormones			X
Tetrachloroethylene	127-18-4	Solvents	U210	X	
Thallium	7440-28-0	Metals		X	
Toluene	108-88-3	Solvents	U220	X	
Trichlorophenol, 2,4,5-	95-95-4	Antimicrobial	On U list with note to see F027		
Warfarin	81-81-2	Other drugs			X
Total: 61		Count -->	32	35	16

Source: OIG review of EPA's 352 unassessed biosolids pollutants, RCRA hazardous list, EPA priority pollutants, and NIOSH hazardous drugs list.

Agency Comments on Draft Report and OIG Evaluation



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 04 2018

MEMORANDUM

SUBJECT: Response to August 2, 2018, Office of Inspector General's Draft Report, "Weaknesses in the EPA's Biosolids Program Threaten the Agency's Mission to Protect Human Health and the Environment"

FROM: David P. Ross, Assistant Administrator
Office of Water

Handwritten signature of David P. Ross.

Susan Parker Bodine, Assistant Administrator
Office of Enforcement and Compliance Assurance

Handwritten signature of Susan Parker Bodine.

TO: Kevin Christensen, Assistant Inspector General
Office of Audit and Evaluation

Thank you for the opportunity to respond to the issues and recommendations presented in the Office of Inspector General (OIG) Draft Report (OPE-FY17-0019) regarding the implementation of controls over the land application of sewage sludge (biosolids). While we appreciate the OIG conveying the challenges on how the Environmental Protection Agency (EPA) implements the biosolids program, the Agency is disappointed in the process the OIG used to develop the recommendations and report. The Office of Water (OW), in particular, had numerous discussions with the OIG yet almost none of our input has been taken regarding conclusions drawn from the OIG investigation. We are equally disappointed that the OIG chose to not grant our request for a two-week extension to submit our response.

We are particularly concerned about how the science is presented in the OIG report. It is biased and raises alarm due to the use of narrowly selected studies and examples, and information that is taken out of context or that is not relevant to the Clean Water Act (CWA) statutory requirements. Also, the subject is presented in a scientifically debatable manner. There is no

attempt to make it clear to the reader that the occurrence of pollutants in biosolids does not necessarily mean that those pollutants pose a risk to public health and the environment.

We agree there is a need to address the uncertainty of potential risk posed by pollutants that are found in biosolids, and we have made that a top priority for our biosolids program. We also agree that there are other biosolids efforts that can be improved upon. It can be challenging to communicate information about public health and environmental risk, particularly when risks have not been fully evaluated, as is the case for many contaminants found in biosolids. However, we disagree with the OIG characterizing uncertainties in science as known risks or “threats” to human health and the environment. We also disagree with the OIG prescribing new policy or specific science-based measures as opposed to addressing how the EPA meets its statutory requirements. We also would encourage the OIG to present improvements and acknowledge progress that has been made by the Agency.

If you have questions, please contact Steven Moore at Moore.Steven@epa.gov or Gwendolyn Spriggs at Spriggs.Gwendolyn@epa.gov.

Attachment

AGENCY'S RESPONSE TO REPORT RECOMMENDATIONS

Recommendation No. 1

The OIG recommends OECA develop and implement a method to capture and analyze biosolids inspections data in the EPA's data system of record for any biosolids inspection activities that are conducted during the National Pollutant Discharge Elimination System (NPDES) permit inspections.

The EPA concurs with the intent behind this recommendation. We would note that the EPA NPDES data system (ICIS-NPDES) already has the capability to identify NPDES inspections with biosolids components. The EPA's regulations require authorized NPDES programs to have "inspection and surveillance procedures to determine, independent of information supplied by regulated persons, compliance or noncompliance with applicable program requirements." See 40 CFR 123.26(b). For example, the EPA Regions and states can use ICIS-NPDES to record "Desk Audits." See ICIS-NPDES screenshot below (from "Add Inspection/Evaluation" data entry screen).²⁷

* Federal Statute
Clean Water Act

* Law Sections
1 selected
✓ Check all ✗ Uncheck all
CWA : 308[A][B] : Records and Reports; Inspections : NPDES - Pretreatment
✓ CWA : 308[A][B] : Records and Reports; Inspections : NPDES - Sludge/Biosolids
CWA : 308[A][B] : Records and Reports;

* Added Programs
✓ NPDES - Sludge/Biosolids
Program Description

* Compliance Monitoring Type
1 selected
✓ Check all ✗ Uncheck all
✓ Desk Audit
Ecological Effects Data Audit
Financial Record Review
Health Effects Data Audit
Non-Financial Record Review

Enter if Biomonitoring is selected as the Compliance Monitoring Type
Biomonitoring Compliance Monitoring Method

With respect to analyzing biosolids inspections data that is reported to ICIS-NPDES, the EPA ECHO system allows the EPA, states, and the public to identify who was subject to a biosolids inspection, the lead inspection agency, and date of inspection. See: <https://echo.epa.gov/facilities/facility-search?mediaSelected=bio>

²⁷ An Off-site Desk Audit is a comprehensive off-site compliance evaluation of information, data, records, and facility reports to make a facility-level or program-level (for pretreatment and Municipal Separate Storm Sewer Systems) compliance determination.

Enforcement and Compliance

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Time Since Last Biosolids Inspection

☐ No Restrictions
 ☐ Never Inspected
 ☒ Within
 ☐ None Within

1 Year(s)

Date From: MM/DD/YYYY To: MM/DD/YYYY

By Agency: ☒ Any ☐ EPA ☐ State

Biosolids Inspection Type

DIA - Diagnostic
 DSA - Desk Audit
 FLP - Follow-Up
 FOC - Focused

In response to the apparent concern about biosolids inspection activities that occur as part of a NPDES facility inspection (as opposed, it would seem, to an inspection only of biosolids activities), OECA will include, as a part of its next annual reporting plan memo to the Regional offices, a reminder to Regions to record any biosolids inspection that occurs as part of a larger facility inspection. The EPA will also remind the eight states authorized for the Federal biosolids program to share biosolids inspection data with the EPA NPDES data system (ICIS-NPDES).²⁸ Authorized NPDES programs are required to share these data with the EPA in a timely, accurate, complete, and consistent format (see Subpart C to 40 CFR part 127).

Recommendation No. 2

The OIG recommends OECA establish a nationally consistent and measurable goal for biosolids inspections and nationally consistent desk audit requirements that apply equally to the EPA and authorized states.

The EPA concurs in part with this recommendation. The report noted that the requirements are "more stringent" for the eight authorized states. The compliance monitoring goal established in the NPDES Compliance Monitoring Strategy (CMS) for states with biosolids program authorization requires *either* one comprehensive inspection *or* one off-site desk audit every five years for major POTWs (i.e., biosolids generators) and all regulated use and disposal facilities for a traditional CMS. Facilities that are selected for an off-site desk audit must meet certain criteria. Plans utilizing off-site desk audits, consistent with those criteria, in lieu of inspections are still considered traditional CMS Plans. There are flexibilities inherent in the 2104 CWA NPDES CMS, however, that would allow a state to use other criteria as part of an alternative CMS. For FY18, none of the 8 authorized states submitted an alternative

²⁸ The eight states authorized to administer the Federal biosolids program are: Arizona, Michigan, Ohio, Oklahoma, South Dakota, Texas, Utah, and Wisconsin. See: <https://www.epa.gov/npdes/npdes-state-program-information>

plan. To address the perception that the requirements are more stringent for authorized states, OECA will provide outreach to the states, reminding the states of the flexibilities offered in our compliance monitoring strategies. EPA does not concur on the need to revise requirements for desk audits and annual report reviews; the existing performance standards and record keeping and reporting requirements in the rule ensure consistent review.

With regards to the recommendation regarding nationally consistent desk audit requirements, the EPA does not concur. In the 42 states where the EPA is the Permitting Authority, compliance monitoring activities are conducted in accordance with the plans and protocols established by the EPA Biosolids Center of Excellence. The Center Implementation Plan utilizes off-site desk audits as the main compliance monitoring activity. Once every five years, an in-depth review of each facility's annual report, which is submitted electronically to the EPA, is performed by the Center to determine compliance at the facility in accordance with traditional CMS goals. The biosolids rules include straight forward performance standards and recordkeeping and reporting requirements that provide more transparency and accountability, allowing for consistent review nationwide. Thus, the EPA CMS goals for biosolids are met.

Recommendation No. 3

The OIG recommends that OW complete development of the probabilistic risk assessment tool and screening tool for biosolids land application scenarios.

The EPA concurs with this recommendation. The CWA requires the EPA to identify pollutants found in biosolids, determine whether pollutants found present risk to human health and the environment, and regulate those pollutants that pose risk. Work is already underway to complete tools needed to perform risk assessments on pollutants found in biosolids. The Biosolids Screening Tool identifies pollutants, pathways (e.g., drinking water ingestion, produce ingestion) and receptors (e.g., adult, child) of greatest interest and informs decisions about the need to perform more refined risk assessments, or to address data gaps or uncertainties. Chemicals found in biosolids that do not pass screening will be prioritized and refined risk assessments will be done using a multimedia, multipathway, multireceptor, probabilistic risk assessment (PRA) modeling framework.

Recommendation No. 4

The OIG recommends that OW develop and implement a plan to obtain the additional data needed to complete risk assessments and finalize safety determinations on the 352 identified pollutants in biosolids and promulgate regulations as needed.

The EPA concurs with this recommendation. The CWA requires the EPA to determine whether pollutants found in biosolids pose a risk to human health and the environment. Work is already underway to obtain the data needed to complete risk assessments. For example, data are obtained from the extensive literature search and review conducted as part of the development of biennial reviews. In addition, data are developed through collaborative research with biosolids stakeholders (e.g., Water Research Foundation).

Recommendation No. 5

The OIG recommends that until risk assessments are complete for the unassessed pollutants found in biosolids, OW should conduct studies to determine the effect and impact over time of these pollutants in land-applied biosolids.

The EPA does not concur with this new science and policy recommendation. The OIG is prescribing studies that divert critical resources that are needed to determine potential risk from pollutants already identified in biosolids, something that the OIG also recommends needs to occur.

As stated previously, OW is already working to develop tools and obtain the additional data needed to complete risk assessments on pollutants found in biosolids. The risk assessment process is an extensive process. For a human health risk assessment, the EPA begins the process with planning and research. Then there is an examination of whether a stressor has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances. The EPA then examines the numerical relationship between exposure and effects. When assessing exposure, the EPA examines what is known about the frequency, timing and levels of contact with a stressor. It is during this part of the process that the EPA models pollutants over time under various field conditions. Finally, the EPA examines how well the data support conclusions about the nature and extent of the risk from exposure to the pollutant. Similarly, for ecological risk assessments, the EPA begins with planning and research, then gathers information to help determine what is at risk (in terms of plants and animals) and needs to be protected. Analysis is conducted to determine what plants and animals are exposed and to what degree, and if that level of exposure is likely or not to cause harmful ecological effects. Finally, risk and uncertainties are characterized. A risk assessment typically takes one to two years depending on data availability, peer review comments, and public comments.

Recommendation No. 6

The OIG recommends that OW complete and publish all future biosolids biennial reviews, including the 2017 biennial review, prior to the next review required by the CWA.

The EPA concurs with this recommendation. The CWA requires the EPA to identify additional pollutants found in biosolids every two years. The OW accomplishes this through biennial reviews. When developing biennial reviews, the EPA conducts an extensive literature search then collects and reviews the publicly available information on the occurrence, fate and transport in the environment, human health and ecological effects, and other relevant information for toxic pollutants that may occur in U.S. biosolids. Results are published one year after completion of the biennial review process. The literature search for the 2017 Biennial Review was conducted for January 2016 through December 2017. The OIG implies in the report that the 2017 Biennial Review is late when it is on schedule to be published on time, in December 2018. In addition, OW has established a performance measure for timely completion of biennial reviews. This performance measure emphasizes OW commitment and accountability for the biosolids program and meeting the CWA requirement. This should be acknowledged by the OIG in the report.

Recommendation No. 7

The OIG recommends that OW publish guidance on the methods for the biosolids pathogen alternatives 3 and 4.

The EPA concurs with this policy recommendation. The methods for pathogen determination outlined for Alternatives 3 and 4 are currently listed in Part 503.8(b). The OW is already working with the EPA Office of Research and Development to update the 2003 *Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge* document. The update would include the EPA Methods 1680, 1681 and 1682 which are currently not listed in the guidance document because these methods were approved in 40 CFR Part 136 after the last revision.

Recommendation No. 8

The OIG recommends that OW issue guidance on what new technologies are allowable options or alternatives for biosolids pathogen reduction.

The EPA does not concur with this new policy recommendation. Although the EPA does not currently have guidance, the Agency has a process in place that fully addresses this OIG recommendation. The EPA's Pathogen Equivalency Committee (PEC) already makes determinations on a case-by-case basis for new alternatives for pathogen reduction. The site-specific or national equivalencies already approved, along with all the necessary requirements for each approval, are listed on the biosolids webpage and can be used as guides and examples:

<https://www.epa.gov/biosolids/examples-equivalent-processes-pfrp-and-psrp>. There are various new technologies that were granted national equivalency which means that the technologies can be used anywhere. The site-specific equivalencies for new technologies also can be used by other facilities, however protocol testing would be required and those facilities would be granted an equivalency of their own once approved by the PEC.

As part of the equivalency process, the EPA requires an approved and endorsed quality assurance project plan (QAPP) from applicants, and protocol testing. This ensures that the proposed process or technology can perform at full scale. If applicants have a QAPP that needs minimal changes and if they adhere to the QAPP during testing, costs would be lower and the Pathogen Equivalency Committee (PEC) evaluation process could take less time. In addition, QAPPs used for site-specific and national equivalencies already approved and listed on the EPA website can be used as guides or modified and used as needed.

Recommendation No. 9

The OIG recommends that OW issue updated and consistent guidance on biosolids fecal coliform sampling practices.

The EPA concurs with this policy recommendation. The guidance assists in the implementation of 40 CFR Part 503 requirements. The OW is already working with the EPA Office of Research and Development to update the 2003 *Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge* document.

Recommendation No. 10

The OIG recommends that OW change the website response to the question “Are biosolids safe?” to include that the EPA cannot make a determination on the safety of biosolids because there are several unregulated pollutants found in the biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.

The EPA concurs with this policy recommendation. The OW is already revising the entire EPA biosolids website to ensure information is updated and made clearer. The response to the Frequently Asked Question “Are biosolids safe?” was changed in mid-July 2018 from the 1996 National Research Council’s concluding remarks to the National Research Council’s 2002 overarching finding: *“There is no documented scientific evidence that the Part 503 rule has failed to protect public health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids.”*

Recommendation No. 11

The OIG recommends that OW modify the EPA website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question “Are biosolids safe?” These changes should stay in place until the EPA can assess risk of all unregulated pollutants found in biosolids.

The EPA does not concur with this new policy and science recommendation. The OW already posts information on the website on unregulated pollutants found in biosolids and discloses data gaps in the biennial reviews. Data gaps and uncertainties are also characterized as part of the risk assessment process. As stated previously, OW is making extensive revisions to the biosolids website to ensure that information is updated and made clearer. The OW is working to develop tools and obtain the additional data needed to complete risk assessments on pollutants found in biosolids.

Recommendation No. 12

The OIG recommends that OW issue guidance to include the website address for information on unregulated pollutants in biosolids as part of the required biosolids label and information sheets provided with biosolids distributed or sold to the public and industrial sources for land application.

The EPA does not concur with this new policy recommendation. This recommendation seems to request that biosolids product labels refer people to the EPA website that identifies the unregulated contaminants found in biosolids. However, in the report the OIG recommends the EPA add new labeling requirements to biosolid products that identify specific unregulated contaminants in each product available for purchase so the consumer can make informed decisions. Contaminants in biosolids products will vary, depending upon the source of the biosolids and over time. There is no statutory requirement under CWA Sec 405 to provide any information on specific regulated or non-regulated pollutants in biosolids on biosolids labels and information sheets, beyond the scope of the labeling requirements in 503.14(e) which state: *“Either a label shall be affixed to the bag or other container in which sewage sludge that is*

sold or given away for application to the land, or an information sheet shall be provided to the person who receives sewage sludge sold or given away in another container for the application to the land. The label or information sheet shall contain the following information: (1) the name and address of the person who prepared the sewage sludge that is sold or given away in a bag or other container for application to the land; (2) A statement that application of the sewage sludge to the land is prohibited except in accordance with the instructions on the label or information sheet; and (3) the annual whole sludge application rate for the sewage sludge that does not cause any of the annual pollutant loading rates in Table 4 of § 503.13 to be exceeded.”

Recommendation No. 13

The OIG recommends that OW conduct regular biosolids training and conference calls or meetings for regional and state staff and wastewater treatment operators to improve consistency in rule interpretation and aid in knowledge transfer.

The EPA concurs with this policy recommendation. There are already monthly biosolids calls with biosolids leads in the EPA offices and regions. The EPA attends the Water Environment Federation’s National Biosolids Partnership (NBP) quarterly State and Regional Biosolids Coordinators calls; and the NBP Advisory Committee Update Calls. In addition, the EPA participates on regular calls with other biosolids stakeholders (e.g., National Association of Clean Water Agencies (NACWA), North East Biosolids and Residuals Association, and others).

Recommendation No. 14

The OIG recommends that in the absence of additional EPA technical biosolids trainings or conferences, direct the Biosolids Center of Excellence to start and maintain on the EPA website a repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve knowledge transfer to the EPA regional and state biosolids program managers as well as wastewater treatment plant operators.

The EPA does not concur with this new policy recommendation. OW already documents and consolidates public and stakeholder inquiries and makes them available to biosolids contacts in the EPA offices and regions, and will continue to emphasize this knowledge transfer.

In addition, the Center is principally a compliance monitoring and enforcement center, established with the goal of maintaining a presence within the regulated community, evaluating compliance, and enforcement of the laws and regulations. On page 6 of the OIG report, the header “*EPA’s Federal Biosolids Program Management*” seems to imply the Center has a broader role than compliance assurance and enforcement. We recommend the title be modified to reflect this limited role. The first sentence in this section also needs to be modified to correctly reflect the Center’s scope of responsibility; rather than refer to the EPA’s “oversight of the land application of biosolids,” it should say “oversight of biosolids compliance monitoring and enforcement.”

CLARIFYING INFORMATION REGARDING REPORT FINDINGS

The OW and OECA appreciate the opportunity to provide clarification and recommendations to inform the report's findings.

- Report Title: “*Weaknesses in the EPA’s Biosolids Program Threaten the Agency’s Mission to Protect Human Health and the Environment.*” There is no scientific basis for the title of the OIG report. Since the OIG initiated its investigation on the biosolids program a year ago, they have referred to their investigation during meetings and conference calls, in their monthly status reports, the March OIG Discussion Document, and even the electronic file name for this final report as, “*EPA’s Controls Over the Land Application of Sewage Sludge (OPE-FY17-0019).*” The EPA recommends that the report title be changed back to the original title.
- The OIG neglects to mention the beneficial use of biosolids anywhere in the report. Multiple studies have stated that when applied at the appropriate agronomic rate, biosolids can increase soil organic carbon, increase cation exchange capacity, provide beneficial micronutrients for crops, increase soil aggregate stability, decrease soil bulk density, improve soil resistance to compaction, increase water retention and plant available water, and increase water infiltration which reduces risks for runoff and erosion.²⁹
- *At a Glance:* Reference to the 61 pollutants designated as hazardous, acutely hazardous or priority pollutants in other EPA programs should be deleted in this section and throughout the report.

The OIG states that “*Although the EPA consistently monitored biosolids for nine regulated pollutants, the EPA lacked the data needed to make a determination on the safety of 352 pollutants found in biosolids, including 61 designated as acutely hazardous, hazardous or priority pollutants in other programs.*” This reference to the 61 designated pollutants serves to alarm the reader. The statement speaks to hazard, and hazard alone does not indicate risk. While OW will use toxicity and occurrence data to prioritize pollutants that need to be assessed for risk, there is no direct relationship between these designations and the CWA requirements for biosolids.

- *At a Glance:* The following statement is inaccurate: “*The EPA identified 352 pollutants in biosolids, but cannot consider these pollutants for further regulation due to a lack of data.*” Not all 352 pollutants found in biosolids lack data to evaluate risk. Those pollutants with sufficient data will be evaluated for risk once the Biosolids Screening Tool and the probabilistic risk assessment modeling framework are completed and made public.
- Pages 1-2: The background section under *Environmental and Health Concerns for Land-Application Biosolids* should be deleted. Specific examples from pages 1 and 2 are found in subsequent bullets.

This section is extremely biased and presents the subject in a scientifically debatable manner. The OIG simply and without context lists a series of statements regarding extreme effects, possible

²⁹ North Central Region Water Network. <https://soilhealthnexus.org/soil-quality-impacts-agricultural-municipal-biosolids-applications/>

routes of exposure, and fate of certain pollutants that only serves to alarm the reader. There is no indication that the OIG performed a thorough literature search for their investigation. Instead, the OIG narrowly selects studies, frequently without citation, and conflates toxicity and occurrence with risk. There is no mention of the W3170, a group that consists of researchers from over 20 major universities that collaborate on a wide-range of biosolids research. The participants of the W3170 publish in scientific peer-reviewed journals, present at major conferences and some of the members are part of the U.S. Department of Agriculture's (USDA) Cooperative Extension Service. The group collaborates with the EPA, USDA, utilities and wastewater treatment facilities, associations, and others.

Due to report bias and frequent alarmist language, it is not clear to the reader that the occurrence of pollutants in biosolids does not necessarily mean that those pollutants pose a risk. We readily agree, however, that we need to address the uncertainty of risk from pollutants found in biosolids and we have made that our top priority in the biosolids program.

- Page 2: The National Institute of Occupational Safety and Health (NIOSH) develops guidance on worker health and safety relative to numerous topics. The OIG chose a NIOSH guidance for biosolids handlers and applicators that examined only one field site that *“did not comply with EPA requirements.”* We agree with the NIOSH guidance conclusions that *“Additional study of worker exposures to pathogens and other toxics possibly present in Class B biosolids is needed. This will reduce scientific uncertainty about these issues and allow further refinement of worker precautions.”* This conclusion should be reflected in the OIG report.
- Page 2: The OIG made the uncited statement: *“The Netherlands and some regions of Belgium, Austria and Germany have effectively banned agricultural application of biosolids due to growing public concerns.”* This information is based on the policies of other countries and is not relevant to compliance with the CWA. There is pressure for the Netherlands to keep limited agricultural land available for the land application of livestock manure, and have prioritized manure application over biosolids application.³⁰ The Flemish Region of Belgium,³¹ and Finland³² have policies that also make land available for manure as opposed to biosolids. In Germany, biosolids land application will not be permitted after 2023 for wastewater treatment plants serving more than 50,000 people. There is also indication that economics plays a role for Germany's policy. Germany allows co-combustion of sludge in coal-fired power stations with authorization from the authorities locally but without requiring them to comply with the European Union waste incineration directive (WID). If Germany were made to comply with WID, it could likely be found uneconomical to clean up the coal emissions to WID limits. Further, Germany is a major supplier of incinerators and there is a large number of incinerators in the country.³³ Competition to satisfy this large “grate capacity” has driven

³⁰ Brunet, Huber (Syndicat des Professionnels du Recyclage en Agriculture, France) – email correspondence August 3, 2018.

³¹ Brunet, Huber (Syndicat des Professionnels du Recyclage en Agriculture, France) – email correspondence August 3, 2018.

³² Evans, T.D. (Conference Paper March 2012). Biosolids in Europe.

³³ Jofra Sora, Marta. 2013. Incineration Overcapacity and Waste Shipping in Europe: the End of the Proximity Principle?

down gate fees to the extent that beneficial use of biosolids is more expensive than incineration for some wastewater treatment facilities.³⁴

In addition, the OIG report did not include a list of countries that continue to support the use of land-applied biosolids. For example, France, United Kingdom and Spain are reaching close to 80% of biosolids land application.³⁵ In Italy, about 70% of biosolids are land applied. Some regions in Italy have implemented more stringent limits over the last five years, however there is no talk of a ban.³⁶ Canada has general acceptance of land application of biosolids with questions concerning contaminants occurring more frequently recently, particularly in British Columbia. Acceptance is generally strong in Ontario however, where there is a strong management program with monitoring and enforcement components.³⁷

- Page 2: The OIG listed a series of narrowly selected statements without providing context. No citation was provided for the studies referred to in the following statement: *“Recent scientific studies have demonstrated deleterious hormonal effects, bone tissue abnormalities, and other health impacts on animals grazing on lands that have used sewage sludge as a fertilizer.”*
- Page 3: The following OIG statement is misleading: *“In addition, the rule establishes limits for cumulative and annual pollutant loading rates: the cumulative rate is the maximum amount of an inorganic pollutant that can be applied to an area of land...”* The cumulative rate is for all pollutants, both inorganic and organic. Currently, there are limits for 10 metals (inorganic).
- Page 12: The following OIG statement is unsupported and inaccurate: *“It was not until our early draft report was shared in March 2018 that the EPA took steps to complete its review.”* While OW acknowledges that the 2013 and 2015 Biennial Reviews were not completed in a timely manner, the impetus to complete and publish the reviews was completely independent of the OIG investigation and steps for completion occurred before the OIG investigation was even initiated. In addition, major steps to revise and improve the biennial review process began in Fall 2017 and were concurrent with the finalization of the 2013 and 2015 Biennial Reviews. The 2013 and 2015 Biennial Reviews reflect many of the changes that were made to the process; hence they were completed and posted in May 2018, which was later than anticipated.
- Page 13: Reference to the 61 pollutants designated as hazardous, acutely hazardous or priority pollutants in other EPA programs should be deleted throughout the report. The statement speaks to hazard, and hazard alone does not indicate risk. While OW will use toxicity and occurrence data to prioritize pollutants that need assessed for risk, there is no direct relationship between these pollutant designations made in the other EPA offices and the CWA requirements for biosolids.

³⁴ Evans, T.D. (Conference Paper March 2012). Biosolids in Europe.

³⁵ Brunet, Hubert (Syndicat des Professionnels du Recyclage en Agriculture, France) – email correspondence August 3, 2018.

³⁶ Castiglioni, Alberto (FISE ASSOAMBIENTE, Italy) – email correspondence August 3, 2018.

³⁷ Bonte-Gelok, Shelly (Ontario Ministry of the Environment, Conservation and Parks) – email correspondence August 7, 2018.

- Page 14: The OIG elaborates on OW's delay in releasing the 2013 and 2015 Biennial Reviews. The EPA openly acknowledges that the biennial reviews were not completed in a timely manner as required by the CWA. However, the following information should be included in the report as it explains the process and time needed to complete such reviews:

The biennial review process includes an extensive literature search over a two-year period, with the studies from that literature search then evaluated and appropriate data obtained. Results are published one year after completion of the biennial review process. The literature search for the 2017 Biennial Review was conducted for January 2016 through December 2017. The OIG implies in the report that the 2017 Biennial Review is late when, in fact, it is on schedule to be published on time in December 2018. The OW took major steps to revise and improve the biennial review process beginning in Fall 2017 which was concurrent with the finalization of the 2013 and 2015 Biennial Reviews. The 2013 and 2015 Biennial Reviews reflect many of the changes that were made to the process; hence they were completed and publicly posted later than originally anticipated (May 2018). Finally, OW has a performance measure for biennial reviews. Monthly targets for the measure continue to be met. The OIG should recognize and acknowledge the extensive improvements that OW has made to the biennial review process and the action OW has taken to increase accountability via its performance measure.

- Page 15: The following statement needs to be revised: *"According to the EPA, the tools have been peer reviewed and are expected to be complete by the end of 2018."* The OW has been making significant changes to the probabilistic risk assessment (PRA) framework and screening tool. While both have been peer reviewed previously, OW is evaluating potential additional peer review which would likely delay the completion of the PRA framework and screening tool.
- Page 15: The OIG statement implies that this practice is negative and uncommon: *"Gaps in the research conducted by the EPA have resulted in stakeholders – such as the state programs, wastewater treatment plants and industrial groups – working to determine how improvements can be made to the quality of the biosolids produced."* Internal and external stakeholders work with, and independently of, the EPA on biosolids issues. This is neither a unique situation nor a negative one. Resources and expertise should be leveraged when possible so that more can be accomplished.
- Pages 16-17: The OIG inaccurately states: *"However, the EPA's responses to questions and answers on biosolids safety rely on a 1996 National Academy of Sciences report..."* The biosolids website was changed July 13, 2018 to reflect the National Research Council 2002 report: *"There is no documented scientific evidence that the Part 503 rule has failed to protect public health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids."* Also, as stated previously, OW has already begun efforts to revise the entire biosolids website.
- Page 18: The OIG makes the following inaccurate statement: *"Moreover, the EPA does not disclose in its response that it identified 352 pollutants in biosolids that are not, and cannot, be regulated. The EPA lacks the data necessary to make a regulatory determination and it cannot determine the level at which these pollutants are safe in biosolids."* The OW cannot make a risk determination at

this time, however, the Biosolids Screening Tool and a probabilistic risk assessment framework are being finalized and will assist OW in risk determinations. Further, not all 352 pollutants identified in biosolids lack sufficient data to determine risk. Where data are needed, the EPA is working internally and with federal, state and industry stakeholders to develop the necessary data needed to assess pollutant risk (e.g., efforts on chemicals of emerging concern and per- and polyfluoroalkyl substances; research initiatives; etc.)

- We recommend that the report highlight the improvements the EPA has made in the management of the Federal biosolids annual reports.

The EPA's biosolids regulations (40 CFR part 503) require certain generators of biosolids to file a Sewage Sludge/Biosolids Annual Program Report. This annual report is submitted each February and documents the measures taken to protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants and pathogens that might be present in sewage sludge/biosolids. These reports were previously submitted in non-standard format and in paper to the EPA Biosolids Center of Excellence (Region 7). In accordance with the NPDES Electronic Reporting rule ("NPDES eRule"), the start date for regulated entities to electronically submit this report where the EPA is the authorized NPDES program was December 21, 2016 (see Table 1 to 40 CFR 127.16). These reports are now submitted to the EPA using a secure electronic reporting tool (NPDES Electronic Reporting Tool or "NeT").

The NPDES eRule requires the EPA to calculate participation rates for each authorized NPDES program six months after the deadline for conversion from paper to electronic submissions and annually thereafter [see 40 CFR 127.26(j)]. The EPA calculated the electronic reporting participation rates by the EPA Region for NPDES-regulated entities that submitted the annual report. See Table 1. These calculations were based on those NPDES-regulated entities that electronically submitted their annual report through the EPA "NeT" and those NPDES-regulated entities that submitted their annual report on paper or through non-standard electronic submissions (e.g., via email). For the 2017 Sewage Sludge/Biosolids Annual Program Report, which had a due date of February 20, 2018, the EPA received 2,226 annual reports electronically through NeT. The EPA also received 81 annual reports through paper submissions or non-standard electronic submissions. This equates to an overall electronic participation rate of 96.5%.

With respect to the 81 reports submitted to the EPA on paper or by non-standard electronic submissions, the Agency plans to work with its Biosolids Center of Excellence (Region 7) to contact these filers to ensure they are aware of the electronic reporting requirement. The EPA will offer additional training to these facilities so that they can submit their annual report using the EPA NeT application starting with the 2018 Sewage Sludge/Biosolids Annual Program Report, which has a due date of February 19, 2019.

OIG Draft Report: “Weaknesses in the EPA’s Biosolids Program Threaten the Agency’s Mission to Protect Human Health and the Environment”

Corrective Action Plan (CAP)

Recommendation	Lead Office	CA	Target Date	Corrective Action
1. Develop and implement a method to capture and analyze biosolids inspections data in the EPA’s data system of record for any biosolids inspection activities that are conducted during the National Pollutant Discharge Elimination System permit inspections.	OECA	1	3 rd quarter FY19	OECA already has a method to capture and analyze biosolids inspections in its system of record. OECA will include, as a part of its next annual reporting plan memo to the EPA Regional offices, a reminder to Regions to record any biosolids inspection that occurs as part of a larger facility inspection. The EPA will also remind the eight states authorized for the Federal biosolids program to share biosolids inspection data with the EPA NPDES data system (ICIS-NPDES). ^[1] Authorized NPDES programs are required to share these data with the EPA in a timely, accurate, complete, and consistent format (see Subpart C to 40 CFR part 127).
2. Establish a nationally consistent and measurable goal for biosolids inspections and nationally consistent desk audit requirements that apply equally to the EPA and authorized states.	OECA	2	December 2019	To address the perception that the requirements are more stringent for authorized states, OECA will provide outreach to the states, reminding the states of the flexibilities offered in our compliance monitoring strategies. EPA does not concur on the need to revise requirements for desk audits and annual report reviews; the existing performance standards and record keeping and reporting requirements in the rule ensure consistent review.
3. Complete development of the probabilistic risk assessment tool and screening tool for biosolids land application scenarios.	OW	3	Release screening tool for public review in 2019, followed by probabilistic framework	OW is working to complete development of screening and probabilistic assessment tools for biosolids land application scenarios. OW anticipates releasing the screening tool first, followed by the probabilistic modeling framework.
4. Develop and implement a plan to obtain the additional data needed to complete risk assessments and	OW	4	Screen the 352 pollutants (as data allow) in 2019/2020	OW will continue reviewing environmental fate and effects information to incorporate into risk assessments for pollutants in biosolids. OW will prioritize using the screening tool to determine which pollutants warrant a more refined (i.e., probabilistic) risk assessment and

Recommendation	Lead Office	CA	Target Date	Corrective Action
finalize safety determinations on the 352 identified pollutants in biosolids and promulgate regulations as needed.				take into consideration the 61 chemicals identified as hazardous under other statutes as identified by the OIG.
5. Until risk assessments are complete for the unassessed pollutants found in biosolids, conduct studies to determine the effect and impact over time of these pollutants in land-applied biosolids.	OW	5	N/A	The EPA does not concur with this new science and policy recommendation.
6. Complete and publish all future biosolids biennial reviews, including the 2017 biennial review, prior to the next review required by the Clean Water Act.	OW	6	December 2018	OW is on target to publish the 2017 Biennial Review (i.e., literature search from January 2016 through December 2017) on time.
7. Publish guidance on the methods for the biosolids pathogen alternatives 3 and 4.	OW	7	2020 at the earliest	OW is working with the EPA Office of Research and Development to update the 2003 <i>Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge</i> document to include EPA Methods 1680, 1681 and 1682.
8. Issue guidance on what new technologies are allowable options or alternatives for biosolids pathogen reduction.	OW	8	N/A	The EPA does not concur with this new policy recommendation.
9. Issue updated and consistent guidance on biosolids fecal coliform sampling practices.	OW	9	2020 at the earliest	OW is working with the EPA Office of Research and Development to update the 2003 <i>Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge</i> document.
10. Change the website response to the question "Are biosolids	OW	10	December 2018	OW will complete the update of the EPA biosolids website to ensure information is updated and made clearer.

Recommendation	Lead Office	CA	Target Date	Corrective Action
safe?” to include that the EPA cannot make a determination on the safety of biosolids because there are several unregulated pollutants biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.				
11. Modify the EPA’s website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question “Are biosolids safe?” These changes should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	OW	11	N/A	The EPA does not concur with this new science recommendation.
12. Issue guidance to include the website address for information on unregulated pollutants in biosolids as part of the required biosolids label and	OW	12	N/A	The EPA does not concur with this new policy recommendation.

Recommendation	Lead Office	CA	Target Date	Corrective Action
information sheets provided with biosolids distributed or sold to the public and industrial sources for land application.				
13. Conduct regular biosolids training and conference calls or meetings for regional and state staff and wastewater treatment operators to improve consistency in rule interpretation and aid in knowledge transfer.	OW	13	Ongoing	OW will continue convening monthly biosolids calls with the EPA offices and regions, participating in expert meetings/workshops on biosolids, and attending meetings with biosolids stakeholders.
14. In the absence of additional EPA technical biosolids trainings or conferences, direct the Biosolids Center of Excellence to start and maintain on the EPA website a repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.	OW	14	N/A	The EPA does not concur with this new policy recommendation.

Revised Recommendations and Corrective Actions Plan

The revised corrective actions plan below was submitted by the Office of Water and OECA and modified through subsequent discussions with the OIG in September 2018. The plan represents the position of the Action Officials and has been agreed to by the OIG. The OIG deleted draft report Recommendation 5 and revised Recommendations 1, 11 and 13.

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion Date	Status
1	Utilizing existing tools and capabilities, implement a method or approach to better capture and analyze biosolids inspections data in the EPA's data system of record for any biosolids inspection activities that are conducted during the National Pollutant Discharge Elimination System permit inspections.	OECA already has a method to capture and analyze biosolids inspections in its system of record. OECA will include, as a part of its next annual reporting plan memo to the EPA Regional offices, a reminder to Regions to record any biosolids inspection that occurs as part of a larger facility inspection. The EPA will also remind the eight states authorized for the Federal biosolids program to share biosolids inspection data with the EPA NPDES data system (ICIS-NPDES). [1] Authorized NPDES programs are required to share these data with the EPA in a timely, accurate, complete, and consistent format (see Subpart C to 40 CFR part 127).	6/30/19	R
2	Establish a nationally consistent and measurable goal for biosolids inspections and nationally consistent desk audit requirements that apply equally to the EPA and authorized states.	OECA agrees with the OIG and will issue a policy memo updating the 2014 CMS to incorporate protocols similar to the current practices of the Biosolids Center for Excellence. The revised policy will recognize the availability of new e-reporting technology and will affirmatively allow states that have the capacity to follow those same practices. We will also offer assistance to states that may want to	3/31/19	R

		adopt EPA's e-reporting tool prior to the 2020 deadline. For those states that do not have ICIS e-reporting or other data systems capable of reviewing 100% of the biosolids universe for noncompliance, we will outline the flexibilities offered in alternative plans.		
3	Complete development of the probabilistic risk assessment tool and screening tool for biosolids land application scenarios.	OW is working to complete the screening tool and probabilistic risk assessment framework for biosolids land application scenarios. OW anticipates releasing the screening tool first, followed by the probabilistic modeling framework, after peer and public review.	12/31/21	R
4	Develop and implement a plan to obtain the additional data needed to complete risk assessments and finalize safety determinations on the 352 identified pollutants in biosolids and promulgate regulations as needed.	OW will develop and implement a plan to obtain data needed to complete risk assessments on the 352 identified pollutants found in biosolids. OW will prioritize pollutants using the screening tool to determine which pollutants warrant a more refined (i.e., probabilistic) risk assessment and take into consideration the 61 chemicals identified as hazardous under other statutes as identified by the OIG.	12/31/22	R
5	Complete and publish all future biosolids biennial reviews, including the 2017 biennial review, prior to the next review required by the Clean Water Act.	OW is on target to publish the 2017 Biennial Review (i.e., literature search from January 2016 through December 2017) on time.	12/31/18	R
6	Publish guidance on the methods for the biosolids pathogen alternatives 3 and 4.	OW is working with the EPA Office of Research and Development to update the 2003 Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge document to include EPA Methods 1680, 1681 and 1682.	12/31/20	R

7	Issue guidance on what new technologies are allowable options or alternatives for biosolids pathogen reduction.	The EPA does not concur with this new policy recommendation. This is not a corrective action, however, to provide transparency to the American public, OW is updating the biosolids website to clarify existing information on the Pathogen Equivalency Committee's determinations on alternative technologies for pathogen reduction.	5/31/19	U
8	Issue updated and consistent guidance on biosolids fecal coliform sampling practices.	OW is working with the EPA Office of Research and Development to update the 2003 Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge document.	12/31/20	R
9	Change the website response to the question "Are biosolids safe?" to include that the EPA cannot make a determination on the safety of biosolids because there are unregulated pollutants found in the biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	OW will modify the biosolids website to address the question, "Are biosolids safe?"	11/30/18	U
10	Modify the EPA's website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question "Are biosolids safe?" These changes should stay in place until the EPA can assess	The EPA does not concur with this new science recommendation. This is not a corrective action, however, to provide transparency to the American public, OW is updating the biosolids website to clarify existing information on the identity of unregulated pollutants found in biosolids and associated data gaps. Website updates will also include clarification around the uncertainty of potential risk from unregulated pollutants found in biosolids.	5/31/19	U

	the risk of all unregulated pollutants found in biosolids.			
11	Determine whether the impact on the safety and protection of human health justifies a requirement to include a general disclaimer message on the biosolids labels and information sheets regarding unregulated pollutants and a referral to the website for additional information. Publish the rationale for the determination on the EPA biosolids website.	The EPA does not concur with this new policy recommendation. The OIG's revised policy recommendation #11 is essentially the same recommendation originally made – EPA cannot add a new requirement for biosolids labels or sheets without a regulation change. Publishing a rationale on EPA's website for changing (or for not changing) a regulation without a public process would be a violation of the Administrative Procedure Act (APA). Therefore, this recommendation would also require EPA to take a regulatory action.		U
12	Conduct regular biosolids training and conference calls or meetings for regional and state staff and wastewater treatment operators to improve consistency in rule interpretation and aid in knowledge transfer.	OW will continue convening monthly biosolids calls with the EPA offices and regions, participating in expert meetings/workshops on biosolids, and attending meetings with biosolids stakeholders. These current, ongoing activities often include training specific to biosolids science and management.	12/31/19	R
13	In addition to EPA technical biosolids trainings or conferences, start and maintain a website repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.	The EPA does not concur with this new policy recommendation. This is not a corrective action, however, to provide transparency to the American public, OW is updating the biosolids website to revise existing frequently asked questions to better address the uncertainty of potential risk from unregulated pollutants found in biosolids.	5/31/19	U

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